Great Ships Initiative

GREAT SHIPS INITIATIVE (GSI)
QUALITY ASSURANCE PROJECT PLAN (QAPP)
FOR LAND-BASED TESTS

2010

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1. INTRODUCTION

This Quality Assurance Project Plan (QAPP) describes the activities undertaken by the Great Ships Initiative (GSI) to assure the quality and credibility of its land-based research findings. The plan covers all aspects of quality assurance/quality control (QAQC), including data quality indicators, evaluation processes, performance measures and acceptance criteria; instrument certification and calibration; personnel training requirements; documents and records; data management; and QAQC assessments and response actions.

2. QAPP DISTRIBUTION LIST

Recipients of this QAPP are listed in table 1. The list includes the GSI Principal Investigator and Project Manager, Ms. Allegra Cangelosi; GSI quality management personnel; and GSI biological and operational research members.

3. BACKGROUND

The Great Ships Initiative (GSI) is a regional effort devoted to ending the problem of ship-mediated invasive species in the Great Lakes-St. Lawrence Seaway System and globally. In support of that goal, the GSI has established superlative freshwater ballast treatment evaluation capabilities at three scales—bench, land-based, and on board ship.

The GSI awards its independent status-testing services to developers of ballast treatment systems and processes determined to be promising. GSI status-testing is performed at the scale appropriate to the state of development of the target treatment system, with the goal of facilitating the rapid progression of meritorious ballast treatment systems through the research and development and approval processes to a market-ready condition.

GSI has no involvement, intellectual or financial, in the mechanics, design or market success of the actual treatment systems it tests. To ensure that GSI tests are uncompromised by any real or perceived individual or team bias relative to test outcomes, GSI test activities are subject to rigorous QAQC procedures and documentation. This attention to QAQC assures high quality and credible evaluation of GSI and its findings.

Table 1. QAPP Distribution List.

QAPP Recipient	Project Role	Organization	Contact Information
Ms. Allegra Cangelosi	GSI Principal Investigator & Project Manager	Northeast-Midwest Institute	acangelo@nemw.org
Ms. Nicole Mays	GSI Senior Quality Systems Officer	Northeast-Midwest Institute	nmays@nemw.org
Ms. Kelsey Prihoda	GSI Senior QAQC Officer	Lake Superior Research Institute	KPRIHODA@uwsuper.edu
Dr. Mary Balcer	GSI Senior Zooplankton Scientist and LSRI Team Leader	Lake Superior Research Institute	mbalcer@uwsuper.edu
Dr. Euan Reavie	GSI Senior Phytoplankton Scientist and NRRI Team Leader	Natural Resources Research Institute	ereavie@nrri.umn.edu
Mr. Matthew TenEyck	GSI Lead Investigator for Whole Effluent Toxicity (WET) Tests	Lake Superior Research Institute	mteneyck@uwsuper.edu
Mr. Tyler Schwerdt	GSI Land-Based RDTE Facility Engineer / Operations Manager	AMI Consulting Engineers PA	tyler.schwerdt@amiengineers.com
Mr. Thomas Markee	GSI Senior Chemist	Lake Superior Research Institute	tmarkee@uwsuper.edu
Ms. Heidi Saillard	GSI Microbial Analyst	Lake Superior Research Institute	hsaillar@uwsuper.edu
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Mr. Donald Reid	GSI Land-Based RDTE Facility Biological Operations Specialist	Independent Consultant	donaldreid@rogers.com
Mr. Steven Hagedorn	GSI Database Manager	Lake Superior Research Institute	shagedor@uwsuper.edu

4. PROJECT MANAGEMENT

4.1. Project Organization

The GSI is a project of the Northeast-Midwest Institute (NEMWI)—a Washington, D.C-based private, non-profit, and non-partisan research organization dedicated to the economic vitality, environmental quality, and regional equity of Northeast and Midwest states. The project is carried out collaboratively with contracting entities including the University of Wisconsin-Superior (UW-S), AMI Consulting Engineers, Broadreach Services, and the University of Minnesota-Duluth (UM-D). For purposes of this QAPP, GSI is defined as the testing organization. Figure 1 depicts the GSI's organizational structure.

4.1.1. Principal Investigator and Project Manager

Ms. Allegra Cangelosi of NEMWI is the GSI Principal Investigator and Project Manager (GSI PI). She is also responsible for planning and leading the overall GSI research agenda at the bench, land-based and ship board scales; developing experimental designs; approving quality system documents and standard operating procedures (SOPs); and making all final decisions on GSI land-based facility engineering and operational modifications and upgrades. In coordination with other GSI research team personnel, she is responsible for analyzing GSI experimental outcomes and writing up findings. She is also responsible for lining up the GSI research activities each year and funding to support them, and interaction with the project Advisory Committee, regulatory community and public. She is assisted by Ms. Nicole Mays of the NEMWI in many of these capacities.

4.1.2. Advisory Committee

A GSI Advisory Committee comprises top-level officials of key stakeholder groups, and provides direct input to Ms. Cangelosi, advising GSI award decisions, program direction, finances and fund-raising. The GSI Advisory Committee, which meets 3-4 times a year, includes elected leadership, environmental organizations, port directors and federal officials from the United States and Canada, and industry representatives.

4.1.3. Industry Outreach

The American Great Lakes Ports Association advises the project, assuring that the GSI is meeting the needs of the maritime industry; and coordinating maritime industry and supply chain outreach.

4.1.4. Technical Advisors

GSI draws on advice from many technical advisors. It also calls upon these advisors to review applications for GSI services from time to time. The relationship with these advisors is informal, voluntary, and on an as-needed basis. Experts include marine engineers, process engineers, toxicologists, biologists and test facility operators.

4.1.5. Financial Management

Ms. Amy Brooks, an independent consultant from Broadreach Services, is the GSI Financial Manager. In this role she is responsible for management of all GSI accounts and financial documents. She also works closely with the GSI PI to develop budget projections, planning documents, and financial information for grant applications.

4.1.6. Quality Management Personnel

Ms. Nicole Mays of NEMWI is the GSI's Senior Quality Systems Officer responsible for development and maintenance of the GSI's Quality Management Plan (QMP), Quality Assurance Project Plans (QAPPs) and SOPs, and writing of QAQC annual reports. Ms. Kelsey Prihoda of the UW-S's Lake Superior Research Institute (LSRI) is the GSI's Senior QAQC Officer. She and a GSI Assistant QAQC Officer are responsible for implementing all GSI project-specific QAQC activities including audits and assessments, and write-up of QAQC reports on specific test activities. Ms. Prihoda is also responsible for assisting in the development of SOPs and project-specific QAPPs, and facilitating real-time communication between the research team and Ms. Cangelosi during all test activities.

4.1.7. Senior Research Team Members

Researchers from LSRI and the UM-D's Natural Resources Research Institute (NRRI), among others, provide critical scientific and technical expertise and implementation services to the GSI PI. Dr. Mary Balcer of LSRI is the GSI's Senior Zooplankton Scientist and LSRI Team Leader. In the first role, she is responsible for developing SOPs, coordinating with the GSI Land-Based RDTE Facility Biological Operations Specialist (Mr. Donald Reid) to assure effective zooplankton sample collection and handling at the Land-Based RDTE Facility, and supervision of LSRI technicians in the implementation of relevant SOPs. In the latter role she is the primary contact for and responsible for GSI-related project activities of all the LSRI personnel, including development of budgets, statements of work, scheduling, hiring, and contractual matters.

Mr. Matt TenEyck is the GSI Lead Investigator for Whole Effluent Toxicity (WET) Tests. In this role Mr. TenEyck is responsible for development and implementation of WET testing SOPs. Mr. TenEyck also coordinates the GSI's bench-scale research program and manages LSRI staff involved in these activities.

Dr. Euan Reavie of NRRI is the GSI's Senior Phytoplankton Scientist and NRRI Team Leader. In the first role he is responsible for development of phytoplankton/algal SOPs, coordinating with the GSI Land-Based RDTE Facility Biological Operations Specialist (Mr. Donald Reid) to assure effective phytoplankton sample collection and handling at the Land-Based RDTE Facility, and supervision of technicians in the implementation of relevant SOPs. In the latter role he is the primary contact for and responsible for GSI-related project activities of all NRRI personnel, including development of budgets, statements of work, scheduling, hiring, and contractual matters.

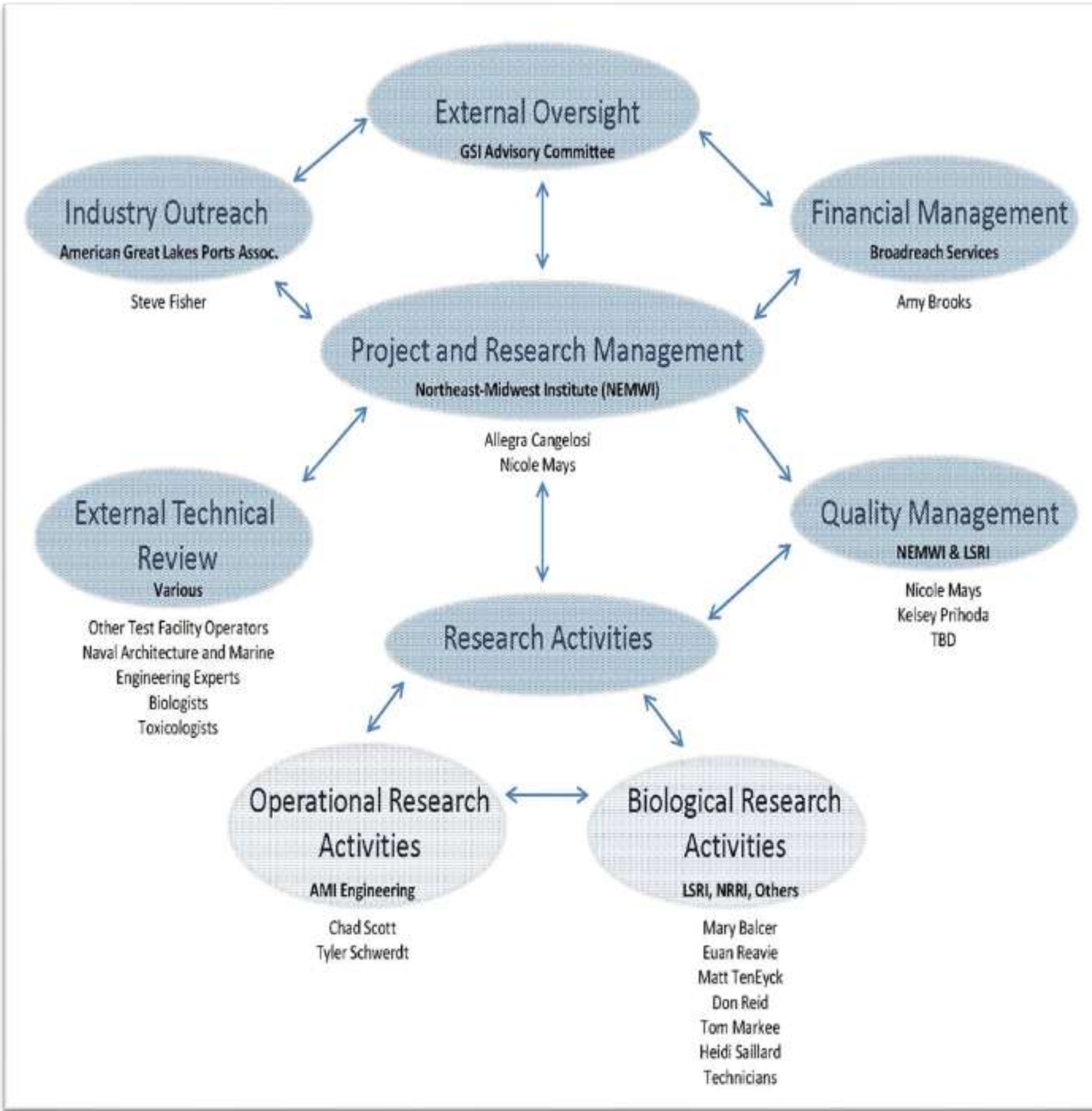
Ms. Heidi Saillard of LSRI is the GSI's Microbial Analyst. In this role she is responsible for development and implementation of the microbial-related SOPs, coordinating with Mr. Donald Reid to assure appropriate microbial sample collection and handling, and analysis of microbial samples according to relevant SOPs. She is advised by Dr. Esther Angert of Cornell University's Department of Microbiology (Ithaca, NY).

Mr. Tom Markee of LSRI is the GSI's Senior Chemist. In this role he is responsible for development and implementation of the chemistry-related SOPs. In addition Mr. Markee works in coordination with the GSI's Lead Investigator for WET Tests (Mr. Matt TenEyck) to help execute SOPs at the bench-scale, particularly those involving active substances.

Mr. Donald Reid is the GSI's Land-Based RDTE Facility Biological Operations Specialist. In this role, Mr. Reid is responsible for implementing biological sample collection operations at the Land-Based RDTE Facility. He is also responsible for development of biological sample collection SOPs, and coordinating with the GSI PI and senior scientists to assure effective sample collection and handling at the Land-Based RDTE Facility. Mr. Reid works closely with Mr. Tyler Schwerdt of AMI Consulting Engineers who is the GSI's Land-Based RDTE Facility Operations Manager. In this role, Mr. Schwerdt serves as the field engineer responsible for operating the GSI Land-Based RDTE Facility and assuring that the facility is properly maintained. Mr. Schwerdt is also responsible for the development of SOPs as they relate to operation of the land-based facility, and coordinating with the GSI PI and senior scientists to assure effective operation of the Land-Based RDTE Facility, generally. He is also responsible for ensuring worker health and safety at the site, coordinating site security and making certain that the facility is correctly winterized at the completion of each operating season. Mr. Schwerdt works under the supervision of Mr. Chad Scott, President and Principal of AMI Consulting Engineers.

Mr. Steve Hagedorn of LSRI is the GSI Database Manager. In this role he is responsible for management of the GSI Biological Research Database and development and implementation of data management SOPs. Mr. Hagedorn works closely with the GSI's senior scientists and QAQC officers.

Figure 1. Organizational Structure of the GSI.



4.2. Projects and Activities

GSI's current suite of projects and activities includes independent third party ballast treatment evaluations at three scales—bench, land-based, and shipboard. Each scale is dedicated to addressing specific evaluation objectives. These include:

GSI Bench-Scale Tests

- Range finding for effective doses under a range of ambient conditions;
- Chemical degradation over time under a range of ambient conditions;
- Detection of any residual toxicity under a range of ambient conditions; and
- Confirmation of treatment process.

GSI Land-Based Tests

- Detection of scale-up, mechanical operation issues;
- Effectiveness of a dose with respect to the full range of ambient organisms; and
- Detection of any whole effluent toxicity.

GSI Shipboard Tests

- Confirmation of biological and operational performance as expected in the ship environment; and
- Confirmation of performance as expected under a broad range of ambient conditions.

GSI testing is performed at the scale appropriate to the treatment state of development, with the goal of helping meritorious ballast treatment systems progress as rapidly as possible to an approval-ready and market-ready condition. Developers of ballast water treatment systems apply for GSI research services online, and awards are offered based on an objective external review process, regardless of the state of development of the proposed treatment. U.S. Environmental Protection Agency Environmental Testing Verification (ETV) testing is performed consistent with ETV protocols, and type-approval testing is conducted consistent with relevant regulatory requirements.

To assure relevancy of test output, GSI test protocols, generally, are as consistent with the International Maritime Organization (IMO) Convention and federal and state requirements as practicable. GSI tests are also third party assessments. They are completely independent of any vested interest in outcomes. Tests are supported by general project funds which derive from federal and state agency grants, Great Lakes port contributions, and in-kind contributions by the local government and universities. None of these funds come to the GSI with any strings other than timely public disclosure of methods and findings.

4.3. Authority

In order to meet its quality system goals and objectives, the following section outlines the specific roles and responsibilities of GSI personnel with respect to the GSI quality system.

GSI Principal Investigator and Project Manager

- Leads GSI research team;
- Approves GSI budget and planning processes, including allocation of adequate resources to GSI's quality system and for personnel training;
- Designs and implements the overall GSI research agenda;
- Approves GSI quality system documents (i.e., QMP, QAPPs, SOPs);
- Issues stop/go orders on day-to-day test activities;
- Issues stop/go orders on any SOP deviations deemed necessary during testing;
- Ensures GSI addresses quality management in all project and activity areas, and that appropriate documentation is developed;
- Ensures GSI complies with this QMP and other quality system documents;
- Maintains an active line of communication with GSI quality management personnel;
- Requires and facilitates implementation of corrective actions and recommendations for improvement; and
- Fosters an atmosphere where quality management practices are a beneficial, integral and requisite part of GSI daily activities.

GSI Quality Management Personnel

- Develop GSI QMPs, QAPPs, and other quality system documents for GSI PI approval;
- Develop and review SOPs for GSI PI approval;
- Facilitate GSI compliance on a day-to-day basis with the QMP, QAPPs and other quality system documents during all test activities;
- Schedule and implement quality system audits and assessments;
- Generate and report results of audit and assessments;
- Monitor and report GSI quality system progress;
- Make recommendations to the GSI PI for GSI quality system improvements.
- Maintain adequate independence and separation from GSI personnel involved in data collection and analysis to assure objective review.

GSI Senior Research Team Personnel

- Support the GSI PI in developing research agenda, and experimental designs;
- Develop relevant methods for inclusion in SOPs;
- Directly implement test activities consistent with GSI quality system documents;
- Help select, schedule and supervise GSI research team members to assure their work is consistent with quality system documents;

- Support development of GSI quality system documents (i.e., QMP, QAPPs, SOPs);
- Ensure GSI addresses and correctly implements quality management in all project areas and that appropriate documentation is developed;
- Maintain active lines of communication with GSI quality management personnel; and
- Implement corrective actions required by the GSI PI in response to GSI QAQC assessments.

GSI Research Team Personnel

- Support senior research team personnel;
- Implement test activities consistent with GSI QAPPs and SOPs;
- Maintain active lines of communication with GSI quality management personnel;
- Respond and report to senior research staff and implement corrective actions that may be required.

5. GSI LAND-BASED BIOLOGICAL RESEARCH ACTIVITIES

5.1. Land-Based RDTE Facility

Land-based biological research activities take place at the GSI's Land-Based Research, Development, Testing and Evaluation (RDTE) Facility located in Superior, Wisconsin (see figures 2 - 4). Testing generally occurs from May to October. Key features of the facility include:

- A freshwater estuary with plentiful aquatic life as the water/organism source;
- Capacity to run water through treatment systems at flow rates of up to 340 m^3/hour;
- A common intake stream that is split into control and treatment tracks for simultaneous and comparable filling of treatment and control retention tanks;
- Capacity to retain water in two pairs of matched 200 m3 control and treatment retention tanks;
- Ability to treat water upon intake, in the tank and/or discharge;
- Flow-controlled in-line sampling;
- Ability to augment source water;
- Ability to discharge water back to the harbor, or to a wastewater treatment tank for subsequent discharge to the sewer.

Figure 2. Location of the GSI's Land-Based RDTE Facility in Superior, Wisconsin.

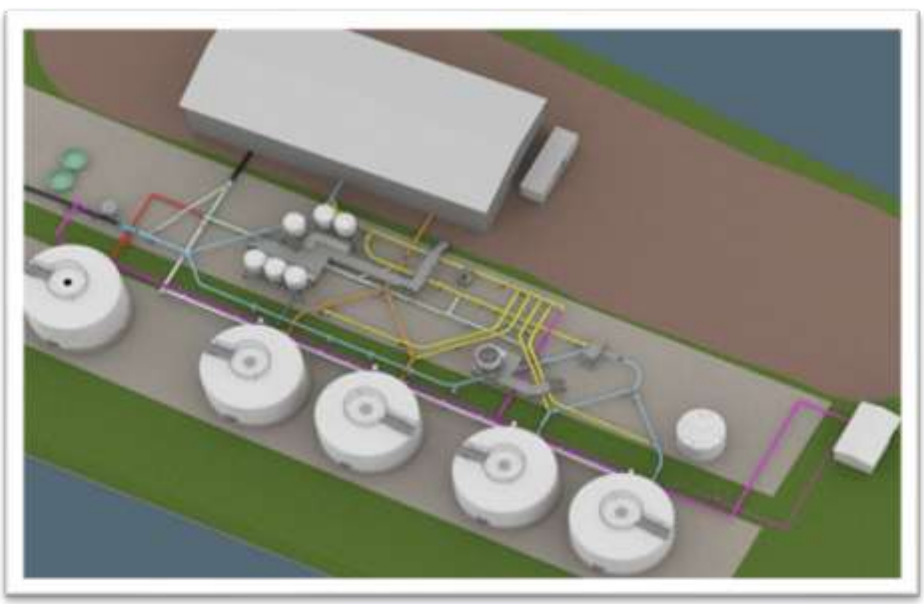


Figure 3. Computer-Generated Rendering of the GSI Land-Based RDTE Facility.

Figure 4. Photo of the GSI Land-Based RDTE Facility.

The GSI's Land-Based RDTE Facility draws raw intake water from Duluth-Superior Harbor at a rate of 400 m^3/hr to 680 m^3/hr. This main flow of intake water can be augmented with solids and/or organisms just prior to being split into control and treatment tracks (see injection points A and B; figure 5).

A Y-split in the intake piping simultaneously channels one half of the flow (200 m^3/hr to 340 m^3/hr) to a treatment track and the other half (also 200 m^3/hr to 340 m^3/hr) to a matched control track (figure 5). The treatment track directs water through the experimental treatment system and into a 200 m^3 cylindrical retention tank (figure 5). The control track by-passes the treatment system and channels water directly into a matched control retention tank (figure 5).

After a retention period, water is discharged sequentially from the treatment and control retention tanks at 340 m^3/hr. The water is directed either back to the harbor, to a 260 m^3 wastewater storage tank for subsequent discharge to the sewer, or recirculated to a second set of facility retention tanks (figure 5).

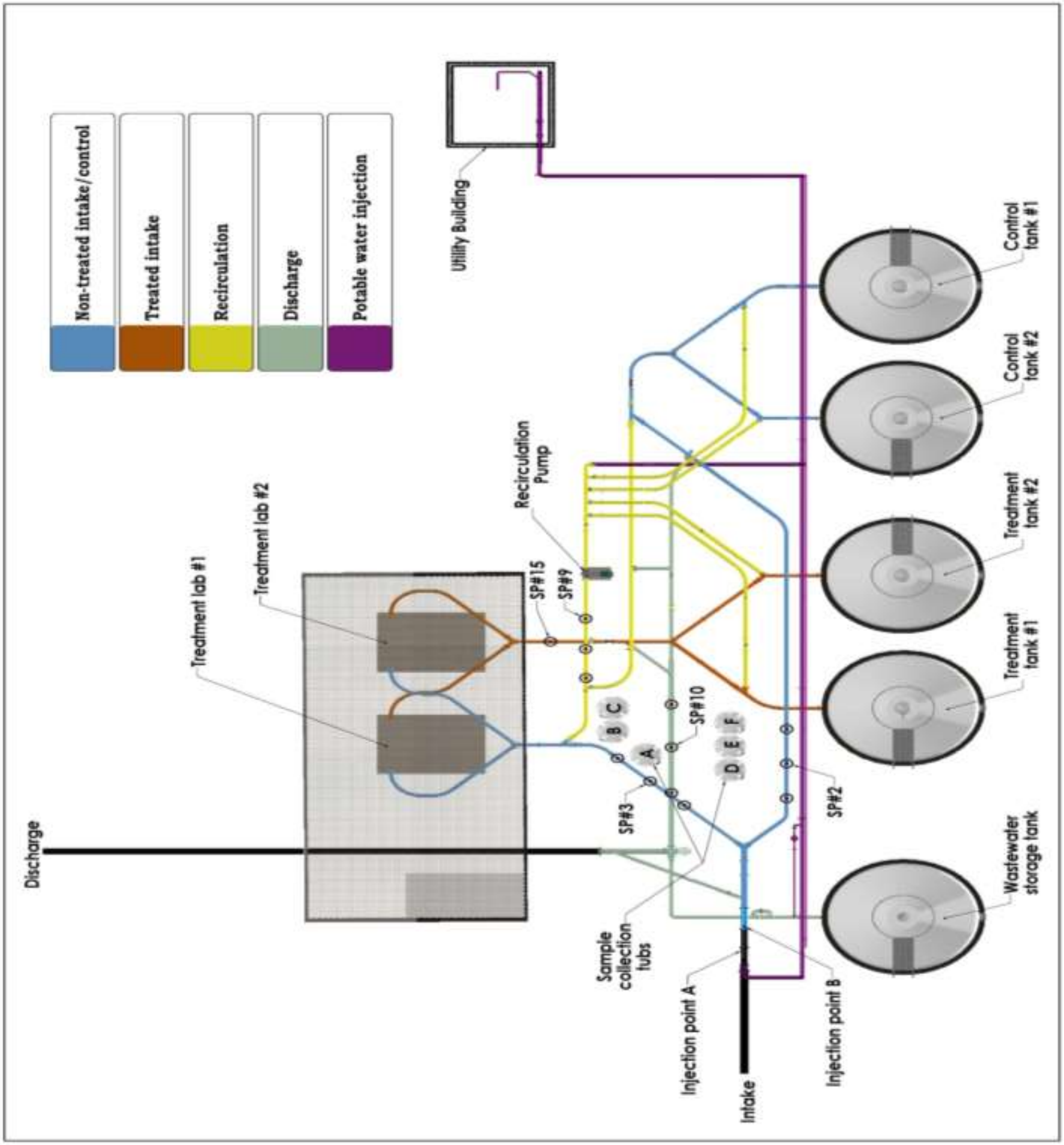


Figure 5. Simplified Schematic of the GSI Land-Based RDTE Facility Showing Location of Sample Points, Injection Points, Retention Tanks, and Treatment and Controls Tracks.

Water is sampled continuously throughout ballasting functions (i.e., intake or discharge) through replicate in-line sample points (SPs). Intake sampling takes place at paired intake sample points (SP#2 and SP#3) on the control and treatment tracks, and immediate post-treatment sampling occurs at SP#15 (figure 5). Discharge sampling is conducted at SP#9 or SP#10 (figure 5). All these SPs, with the exception of SP#15, consist of three sample ports. Other SPs, not shown in figure 5, are used for facility calibration experiments. SPs are generally made up of three identical sample ports spaced at 8' intervals in a length of straight pipe consistent with IMO guidelines. Each port is fitted with a center-located elbow-shaped pitot tube (90^o) which samples the water (figure 6). This pitot design is based on a design developed and validated analytically by the U.S. Naval Research Laboratory in Key West, Florida. The design and lay-out of these replicate sample ports was also validated empirically at GSI, and shown to produce equivalent, representative and unbiased samples of water flow.

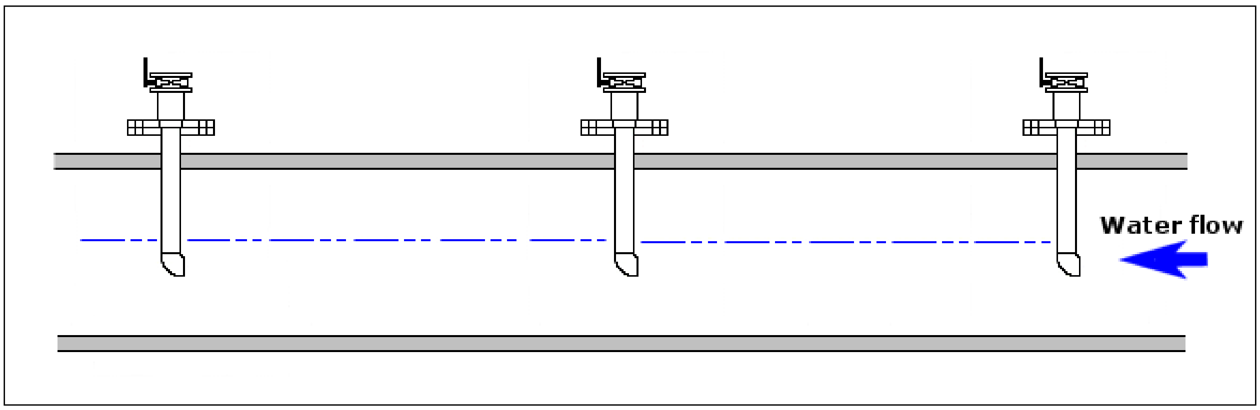


Figure 6. Simplified Schematic of a Sample Point (SP), Showing the Three Sample Ports.

Sample water drawn by sample ports is transferred simultaneously and continuously throughout ballasting operations (intake or discharge) from the sample ports to replicate 3.8 m^3 sample collection tubs via clean 3.8 cm ID flexible hoses and automated flow-controlled pneumatic diaphragm valves. The sample collection tubs, pictured in figure 4, connect to the sample ports in the following arrangement (table 1). (Though the same tubs serve as collection mechanisms for sample flow from more than one pitot, only one such pitot is used at a time during any given sample collection event). The naming convention for individual pitots is: "SP number" plus "position letter". Sample collection tubs are labeled with capital letters.

Table 2. Intake and Discharge Sample Points and their corresponding Sample Port Pitots and Sample Collection Tubs.

	INTAKE							DISCHARGE					
	SP#2			SP#3			SP#15	SP#9			SP#10		
Sample Port Pitot	a	b	c	a	b	c	a	a	b	c	a	b	c
Sample Collection Tub	A	B	C	D	E	F	C & F	C & F	B & E	A & D	C & F	B & E	A & D

An on-site mobile field laboratory (figure 7) and stationary structure (figure 8) provide analysis space to support time sensitive assays associated with the GSI land-based tests, including live analysis of phytoplankton and zooplankton. The laboratories are climate-controlled, and have enough bench space to allow for simultaneous analysis of samples by multiple personnel.

Figure 7. The GSI Mobile Field Laboratory .

Figure 8. The GSI Stationary Laboratory.

5.2. Experimental Design

Test activities at the GSI Land-Based RDTE Facility may have several goals including:

- To determine the effect of scale-up from the bench-scale on treatment outcomes;
- To determine the effectiveness of a specific treatment/dose with respect to the full range of ambient organisms;
- To detect any whole effluent toxicity; and
- To determine the effect of ship-like conditions, including ballast-tank retention, on treatment effectiveness.

SOPs, in conjunction with the GSI QMP and this QAPP are used to implement land-based tests. This facilitates consistent conformance to technical and quality system requirements and increases data quality. The SOPs, outlined in Appendix 1, cover all aspects of GSI land-based testing activities including programmatic and technical processes and procedures such as operation of the GSI Land-Based RDTE facility; sample collection, labeling, analysis and custody; and health and safety.

5.3. Applicable Standards/Criteria

The fundamental approach of GSI land-based testing is to conduct independent, scientifically-sound, rigorous, and quality assured evaluations of ballast water treatment system performance under controlled experimental conditions. In addition, GSI tests are directly relevant to regulatory processes including the IMO Convention, state law, and federal requirements under development in the United States and Canada. To that end, GSI protocols, challenge conditions and testing infrastructure (e.g. flow rate, retention tank size, sample size, sample collection and analysis equipment and data logging) are rooted in the essential features of the IMO G8 guidelines for testing, and the draft Environmental Technology Verification (ETV) protocols under development by the United States Environmental Protection Agency.

With respect to challenge conditions, GSI is fortunate in that its feed water source naturally meets many of the IMO G8 and ETV requirements for intake organism densities and physical/chemical conditions during the testing season (table 4). However, in light of natural variations in source water quality, GSI often augments intake water to assure that initial challenge water conditions meet relevant requirements. For example, ISO 12103-1 fine grade Arizona Test Dust, and concentrated ambient algae harvested from the Duluth-Superior Harbor are metered into the intake stream before the flow split (see injection ports A and B; figure 5), to assure adequate concentrations of Total Suspended Solids (TSS) and live phytoplankton. GSI may also augment intake water to meet Particulate Organic Carbon (POC) and Mineral Matter (MM) requirements. Specific augmentation parameters are provided in the test plan.

GSI testing also can be adapted to address other possible benchmarks such as stricter performance standards or non-regulatory end-points. Table 3 compares GSI test protocols with those of IMO and draft ETV. Table 4 arrays biological, physical and chemical natural and challenge conditions for IMO and ETV testing.

Table 3. Comparison of Key Test Parameters Proposed for GSI Land-Based Tests with IMO G8 and Draft U.S. EPA/ETV Proposed Test Parameters[1].

Parameter	Sub-Category	IMO G8[2]	Draft U.S. EPA ETV[3]	GSI Land-Based Tests
Organisms To Be Evaluated	Zooplankton	Naturally occurring, or cultured species that may be added to the test water.	Ambient assemblage supplemented by the addition of standard test organisms. Ambient population to comprise a minimum of 75 % of the total concentration.	Naturally occurring (i.e. ambient assemblage of Duluth-Superior Harbor).
	Phytoplankton	Naturally occurring, or cultured species that may be added to the test water.	Ambient assemblage supplemented by the addition of standard test organisms. Ambient population to comprise a minimum of 75 % of the total concentration.	Naturally occurring (i.e. ambient assemblage of Duluth-Superior Harbor); or ambient assemblage that may be collected, concentrated, and added to the test water.
	Microbes	Naturally occurring, or cultured species that may be added to the test water.	Ambient assemblage supplemented by the addition of standard test organisms. Ambient population to comprise a minimum of 75 % of the total concentration.	Naturally occurring (i.e. ambient assemblage of Duluth-Superior Harbor).
Intake Organism Diversity & Density	Zooplankton	Organisms ≥50 μm in minimum dimension should be present in a total density of preferably 10^6 individuals but not less than 10^5 individuals per m^3, and should consist of at least 5 species from at least 3 different phyla/divisions.	Total concentration = minimum of 1 x 10^5 organisms/m^3; ambient concentration = minimum of 7.5 x 10^4 organisms/m^3; standard test organism concentration = minimum of 5 x 10^3 organisms/m^3.	Live organisms ≥ 50 μm in minimum dimension should be present in a total density of 100,000 to 1,000,000 live individuals per m^3, and should consist of at least 5 species from at least 3 different phyla/divisions.
	Phytoplankton	Organisms ≥10 μm and less than 50 µm in minimum dimension should be present in a total density of preferably 10^4 individuals but not less than 10^3 individuals per mL, and should consist of at least 5 species from at least 3 different phyla/divisions.	Organisms in the ≥10 μm and <50 μm size class must be present in minimum concentrations of 10^3 organisms/mL with at least 5 species across 3 phyla. Ambient concentration = minimum of 7.5 x 10^2 organisms/mL; standard test organism concentration = minimum of 50 organisms/mL.	Entities ≥10 μm and less than 50 μm in minimum visible dimension should be present in a total density of not less than 500 cells per mL (can be spiked into intake to achieve 1,000-1,800 cells/ per mL), and should consist of at least 5 species from at least 3 different phyla.
	Microbes	Heterotrophic bacteria should be present in a density of at least 10^4 living bacteria per mL.	Organisms in the < 10 μm size class must be present in minimum concentrations of 10^3/mL as culturable aerobic heterotrophic bacteria, with at least 5 species across 3 phyla. Ambient concentration = minimum of 7.5 x 10^2 organisms/mL; standard test organism concentration = minimum of 50 organisms/mL.	Heterotrophic bacteria should be present in a density of at least 1,000 (10^3) MPN per mL.

[1] Comparison is limited to freshwater aspects of the IMO and ETV guidelines only.
[2] IMO MEPC 57, Annex 3: Revised Guidelines for Approval of Ballast Water Management Systems (G8). April 4, 2008.
[3] U.S. Environmental Protection Agency, Environmental Technology Verification Program. DRAFT Generic Protocol for the Verification of Ballast Water Treatment Technologies. March, 2010.

Parameter	Sub-Category	IMO G8[2]	Draft U.S. EPA ETV[3]	GSI Land-Based Tests
Water Quality of Intake/Source Water	N/A	Salinity: <3 PSU; Dissolved Organic Carbon (DOC): >5 mg/L; Particulate Organic Carbon (POC): >5 mg/L; Total Suspended Solids (TSS): >50 mg/L.	Salinity: <1 PSU; Dissolved Organic Matter (DOM): min. 6 mg/L as DOC; Particulate Organic Matter (POM): min. 4 mg/L as POC; Mineral Matter (MM): min. 20 mg/L; Total Suspended Solids (TSS): = POM + MM: min. 24 mg/L; Temperature: 4 – 35 °C.	Dependent on test plan. May include – Salinity: 0 -1 PSU; Dissolved Organic Carbon (DOC): > 6 mg/L; Particulate Organic Carbon (POC): > 5 mg/L; Mineral Matter: > 20 mg/L; Total Suspended Solids (TSS): >24 mg/L; can be artificially augmented to 50 mg/L. Dissolved Oxygen: 5 – 15 mg/L; Temperature: 5 – 25 °C; pH: 7 – 9; Chlorophyll a: 3 – 15 μm/L.
Sample Volume	Zooplankton	At least 20 L of intake water and 1 m^3 of treated water.	Minimum of 3 m^3 concentrated to 1000 mL per sample.	Up to 11.4 m^3, concentrated to approximately 1000 mL per sample.
	Phytoplankton	At least 1 L of intake water and 10 L of treated water.	Minimum of 3 m^3 concentrated to 1000 mL per sample.	At least 1 L per sample.
	Microbes	At least 500 mL of intake water and 500 mL of treated water.	1000 mL per sample.	At least 500 mL per sample.
Number of Intake Samples	Zooplankton	Minimum of 3 samples collected from the treatment track and 3 samples collected from the control track.	1 sample immediately prior to water entry to the control tank and 1 sample immediately before entry to the in-line BWTS, or (if control and challenge water are shown to be representative) one sample before the splitter.	1-3 samples collected from the treatment track and 1-3 samples collected from the control track.
	Phytoplankton	Minimum of 3 samples collected from the treatment track and 3 samples collected from the control track.	1 sample immediately prior to water entry to the control tank and 1 sample immediately before entry to the in-line BWTS, or (if control and challenge water are shown to be representative) one sample before the splitter.	1-3 samples collected from the treatment track and 1-3 samples collected from the control track.
	Microbes	Minimum of 3 samples collected from the treatment track and 3 samples collected from the control track.	. 1 sample immediately prior to water entry to the control tank and 1 sample immediately before entry to the in-line BWTS, or (if control and challenge water are shown to be representative) one sample before the splitter.	1-3 samples collected from the treatment track and 1-3 samples collected from the control track.
Number of Discharge Samples	Zooplankton	Minimum of 3 samples collected from the treatment track and 3 samples collected from the control track.	1 sample from the discharge of the control tank, and 1 sample from the discharge (following any treatments) of the treated water.	1-3 samples collected from the treatment track and 1-3 samples collected from the control track.
	Phytoplankton	Minimum of 3 samples collected from the treatment track and 3 samples collected from the control track.	1 sample from the discharge of the control tank, and 1 sample from the discharge (following any treatments) of the treated water.	1-3 samples collected from the treatment track and 1-3 samples collected from the control track.
	Microbes	Minimum of 3 samples collected from the treatment track and 3 samples collected from the control track.	1 sample from the discharge of the control tank, and 1 sample from the discharge (following any treatments) of the treated water.	1-3 samples collected from the treatment track and 1-3 samples collected from the control track.

Parameter	Sub-Category	IMO G8[2]	Draft U.S. EPA ETV[3]	GSI Land-Based Tests
Analytic Endpoints: Discharge Density	Zooplankton	Less than 10 viable organisms per m^3 greater than or equal to 50 µm in minimum dimension for treated water; more than 100 viable organisms per m^3 greater than or equal to 50 µm in minimum dimension for control water.	Treatment efficacy will be determined by the measurement of living ambient organism concentrations in the treatment discharge. Minimum concentration in control tank discharge is 100 live organisms/m^3.	Dependent on test plan. May include control vs treatment, intake vs discharge, treatment discharge vs regulatory standard (i.e., IMO and/or ETV).
	Phytoplankton	Less than 10 viable organisms per mL less than 50 µm in minimum dimension and greater than or equal to 10 µm in minimum dimension for treated water; more than 100 viable organisms per mL less than 50 µm in minimum dimension and greater than or equal to 10 µm in minimum dimension for control water.	Treatment efficacy will be determined by the measurement of living ambient organism concentrations in the treatment discharge. Minimum concentration in control tank discharge is 100 live organisms/mL.	Dependent on test plan. May include control vs treatment, intake vs discharge, treatment discharge vs regulatory standard (i.e., IMO and/or ETV).
	Microbes	Less than 1 colony forming unit (cfu) per 100 mL or less than 1 cfu per 1 g (wet weight) zooplankton of Toxicogenic *Vibrio cholerae* (O1 and O139), less than 250 cfu per 100 mL of *E. coli*, and less than 100 cfu per 100 mL of intestinal *Enterococci* for treated water; more than 10 cfu per 100 mL or more than 10 cfu per 1 g (wet weight) zooplankton of Toxicogenic *Vibrio cholerae* (O1 and O139), more than 2500 cfu per 100 mL of *E. coli*, and more than 1000 cfu per 100 mL of intestinal *Enterococci* for control water.	Treatment efficacy will be determined by the measurement of living ambient organism concentrations in the treatment discharge. Minimum concentration in control tank discharge is 5×10^2/mL.	Dependent on test plan. May include control vs treatment, intake vs discharge, treatment discharge vs regulatory standard (i.e., IMO and/or ETV).
Water Quality Measurements	N/A	pH, temperature, salinity, dissolved oxygen, TSS, DOC, POC and turbidity (NTU) should be measured at the same time that the samples are collected.	Temperature, salinity, TSS, POM, DOM, mineral matter, dissolved oxygen, pH, chlorophyll a.	Dependent on test plan. May include salinity, DOC, POC; Mineral Matter; TSS, dissolved oxygen; temperature, pH and chlorophyll *a*.
Toxicity	N/A	Separate samples should be collected for toxicity testing of treated water, from the discharge, for systems that make use of Active Substances and also for those which could reasonably be expected to result in changes to the chemical composition of the treated water such that adverse impacts to receiving waters might occur upon discharge. Tests should conducted in accordance with paragraphs 5.2.3 to 5.2.7 of the Procedure for Approval of Ballast Water Management Systems That Make Use of Active Substances (resolution MEPC.126(53)) as amended.	Toxicity tests will be conducted for treatments involving biocides. Tests will be selected from a short list of U.S. EPA standard tests.	Dependent on test plan. E.g., Whole effluent toxicity (WET) tests using treatment discharge water for treatments involving active substances.

Parameter	Sub-Category	IMO G8[2]	Draft U.S. EPA ETV[3]	GSI Land-Based Tests
Biological Sample Analysis	N/A	Samples should be analyzed as soon as possible after sampling, and analyzed live within 6 hour or treated in such a way as to ensure that proper analysis can be performed. Widely accepted standard methods for the collection, handling, storage, and analysis of samples should be used.	Zooplankton enumeration: Concentrate using 35 um mesh plankton nets; no preservation; sub-sample into well plate (20 1mL wells observed); observe with dissecting microscope and probe organisms to determine live/dead status; fix with lugol's for total counts. Phytoplankton enumeration: No preservation; stain with Fluorescein Diacetate and CMFDA; load into a Sedgewick Rafter Counting Chamber and examine under epifluorescence using a FITC narrow pass filter cube. Bacteria: Plate on appropriate media; use a DNA colony blot hybridization for V. cholerae.	Direct counts (number live) for treatment discharge samples, indirect counts (number of dead and total) for intake and control discharge samples for organisms in the >50 μm size class; direct counts (number of live) using Fluorescein Diacetate (FDA) vital stain for organisms in the 10-50 μm size class; enumeration (using appropriate media)of total viable heterotrophic bacteria, E. coli, and Enterococci and preparation of colony blots for the detection of toxigenic *Vibrio cholerae* for organisms in the <10 μm size class.
Flow Rate	N/A	At least 200 m^3/hr.	At least 200 m^3/hr.	Up to 340 m^3/hr and no lower than 200 m^3/hr.
Number and Capacity of Retention Tanks	N/A	At least 1 control and 1 treatment tank with a minimum capacity of 200 m^3 each.	At least 1 control and 1 treatment tank with a minimum capacity of 200 m^3 each..	2 control and 2 treatment tanks each with a capacity of 200 m^3.
Control/Treatment Cycle Sequence	N/A	Control and treatment cycles may be run simultaneously or sequentially.	Control and treatment cycles may be run simultaneously or sequentially.	Control and treatment cycles run simultaneously or sequentially.
Retention Time	N/A	At least 5 days.	Minimum of one day.	Dependent on test plan.
Number of Trials	N/A	At least 5 successes.	Minimum of three per salinity regime.	Dependent on test plan.
QAQC	N/A	Quality Management Plan (QMP) addressing the quality control management structure and policies of the testing body, including subcontractors and outside laboratories; Quality Assurance Project Plan (QAPP) addressing the specifics of the ballast treatment technology to be tested, the test facility, and other conditions affecting the actual design and implementation of the required experiments.	A Test/Quality Assurance Plan (TQAP), also called a QAPP, is to be compiled by the Testing Organization, with input from the vendor. The TQAP will describe the procedures for conducting a test or study according to the verification protocol requirements for the application of a ballast water treatment system at a particular site. At a minimum, the TQAP shall detail test objectives, specific test procedures (including sample and data collection, sample handling, analysis and preservation), and quality control and assurance requirements (including measures of precision, accuracy, comparability, and representativeness).	Quality Management Plan (QMP) addressing the quality control management structure and policies of the GSI; Quality Assurance Project Plan (QAPP) addressing the specifics of the GSI's ballast treatment tests, its facilities, and other conditions affecting the actual design and implementation of the required experiments. A Test/Quality Assurance Plan (Test Plan), o be compiled with input from the vendor.

Table 4. Ranges of Various Physical/Chemical and Biological Parameters in Ambient Water from Duluth-Superior Harbor (June – September) in Comparison to Draft U.S. EPA/ETV and IMO G8 Recommended Challenge Conditions.

Parameter	DRAFT U.S. EPA ETV[4]	Recommended IMO G8[5]	Historic Ranges Duluth/Superior Harbor	Target Values for Augmented Duluth-Superior Water
Temperature (^oC)	4 – 35	–	5 – 25	5 – 25
Salinity (psu)	< 1	Two salinities, >10 psu difference	0 – 1	0 - 1
Total Suspended Solids (TSS) (mg/L)	Min. 24	> 50	2 – 21	Dependent on test plan.
Particulate Organic Carbon (POC) (mg/L)	Min. 4	> 5	0.5 – 2.1	≥5
Dissolved Organic Carbon (DOC) (mg/L)	Min. 6	> 5	3 – 30	3 - 30
Mineral Matter (MM) (mg/L)	Min. 20	--	--	Min. 20
Zooplankton (> 50 $\mu m/m^3$)	Min. 75,000	> 100,000	100,000 - 3,000,000	100,000 – 3,000,000
Phytoplankton (10 - 50 μm/mL)	Min. 750	> 1,000	25 – 1,200	> 1,000
Heterotrophic Bacteria (CFU/mL)	Min. 750	> 10,000	> 1,000 MPN/mL	1,000 MPN/mL

4 U.S. Environmental Protection Agency, Environmental Technology Verification Program. DRAFT Generic Protocol for the Verification of Ballast Water Treatment Technologies. March, 2010.
5 IMO MEPC 57, Annex 3: Revised Guidelines for Approval of Ballast Water Management Systems (G8). April 4, 2008.

6. QAPP COVERAGE AND PROCESS FOR DEVIATIONS

6.1. QAPP Coverage

This QAPP describes the activities undertaken by GSI to assure the quality and credibility of its land-based research findings. The QAPP is valid from date of PI signature for a period of five years. It will be reviewed annually, with revisions made on an as-needed basis following the annual review.

6.2. Process for Deviations

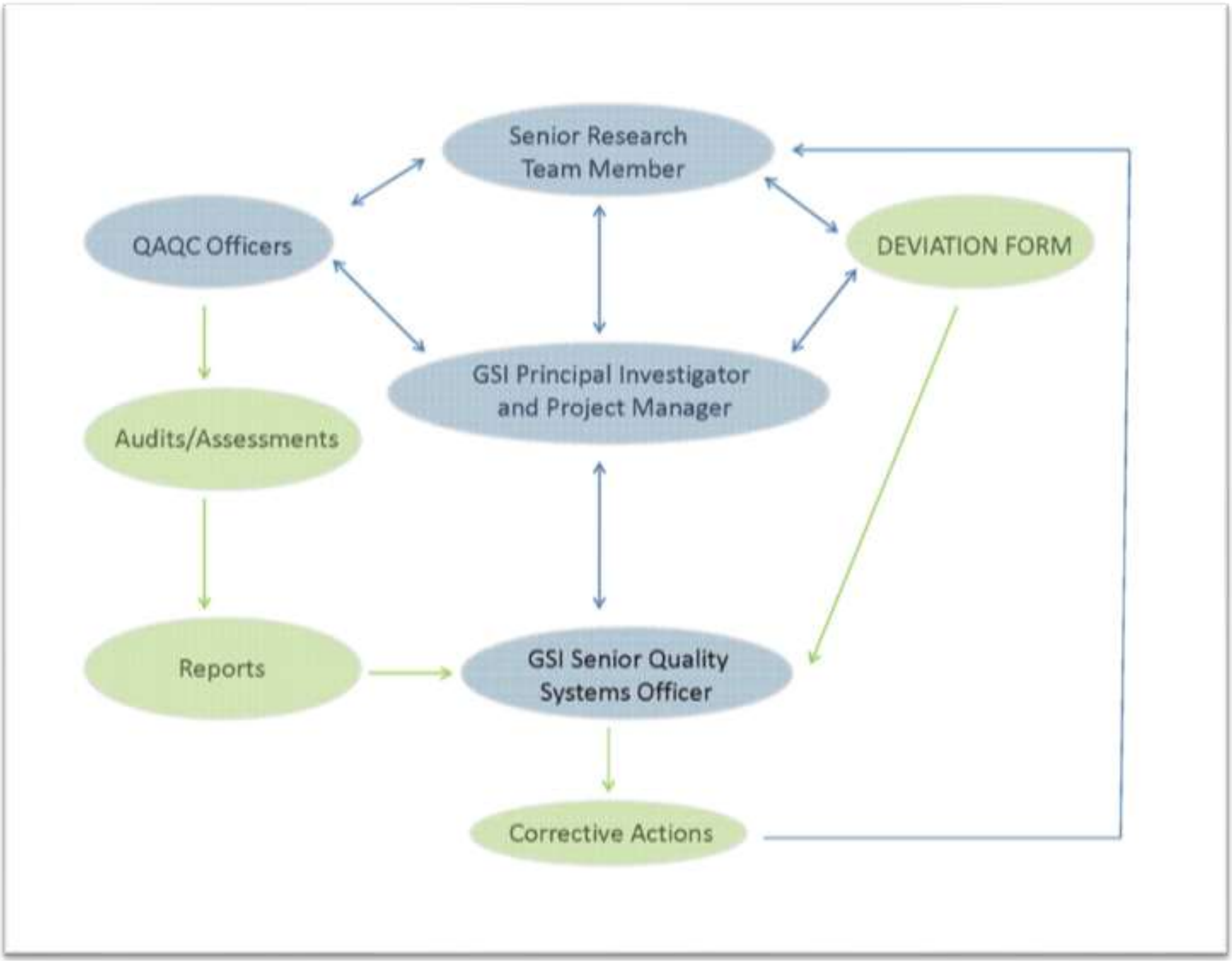
GSI senior research personnel (i.e., Dr. Mary Balcer, Dr. Euan Reavie, Mr. Tom Markee, Ms. Heidi Saillard, Mr. Don Reid, Mr. Tyler Schwerdt and Mr. Matthew TenEyck) are responsible for resolving any temporary or day-to-day issues pertaining to implementation of this QAPP and SOPs relevant to GSI land-based testing activities. All known deviations are communicated to the GSI PI as they occur. The GSI PI has sole authority to issue stop/go orders on day-to-day test activities, as well as on any SOP deviations deemed necessary during testing.

Deviations are also communicated to the GSI QAQC officers as they occur, and recorded on a GSI SOP Deviation Form. The form lists the date and time of the deviation, the description of the deviation, any impact on testing, and any corrective actions taken. The deviation form is signed by the GSI PI and the relevant senior research team member. GSI QAQC officers are responsible for maintaining GSI SOP Deviation Forms on file and posting to the GSI SharePoint intranet site for storage and archiving.

Deviations may also be discovered during technical systems audits or during the data verification and validation process. GSI QAQC officers are responsible for assessing the implementation of this QAPP and relevant SOPs during each test of a ballast treatment system and for documenting all evident deviations in a QAQC laboratory notebook that is specific to the treatment technology being tested. At the end of the test duration, the officers provide a report to the GSI Senior Quality Systems Officer and GSI PI. The report includes a table listing deviations to the specific QAPP associated with the testing, as well as a table listing deviations to the specific SOPs that were used during testing. GSI QAQC Officers post final copies of the QAPP and SOP audit reports to the GSI SharePoint website for archiving and storage.

Figure 9 outlines the procedure for communicating deviations to this QAPP and associated SOPs.

Figure 9. Process for Communicating Deviations to this QAPP and Associated SOPs Relevant to GSI Land-Based Testing Activities.
Note: Blue lines = communication; green lines = action.



7. Quality Objectives and Criteria for Measurement Data

GSI uses the U.S. Environmental Protection Agency's principal and secondary data quality indicators to determine data utility relative to its land-based research activities. Data quality objectives and acceptance criteria vary by analysis type and will be specified in the test plan, though summaries are provided in tables 5-10. In general, only data that meet or exceed these criteria is deemed valid, thereby ensuring that all data generated is of the highest quality.

7.1. Precision

Precision is a measure of agreement among repeated measurements of the same property under identical conditions. With respect to GSI activities involving chemistry, water quality, and microbial analyses at the land-based scale of testing, precision is evaluated by analyzing at least 10 percent of samples in duplicate and calculating the Relative Percent Difference (RPD) as determined by the following equation:

$$\mathrm{RPD} = \left(\frac{(|x_1 - x_2|)}{\frac{x_1 + x_2}{2}} \right) *\ 100\ \%$$

where:

x_1= sample
x_2 = duplicate sample

For zooplankton samples collected at the GSI Land-Based RDTE Facility, precision is measured by analyzing at least two slides (i.e., in the case of microzooplankton) or two counting wheels (i.e., in the case of macrozooplankton) from every sample collected. Precision is quantified by calculating the coefficient of variation (CV) for each sample using the following equation:

$$\%CV = \left(\frac{S}{\overline{x}} \right) \times 100\%$$

where:

S= standard deviation
$\overline{x}$ = Mean

For phytoplankton samples collected at the land-based facility, at least three treatment discharge samples and at least one out of ten control intake/discharge samples (from each set of test trials) is selected for evaluation of within-sample precision. Precision is measured by the analysis of at least two subsamples by the same phytoplankton taxonomist. In the event that there are fewer than ten total control samples collected during a treatment technology performance evaluation, a minimum of one discharge control sample is chosen for evaluation of within-sample precision. Precision is quantified by calculating percent similarity (PSC), see section 7.2.3 for equation.

7.2. Bias

Bias refers to the systematic or persistent distortion of a measurement process that causes errors in one direction. It can be generated by the facility, the experiment, and/or the operator. The GSI evaluates bias relative to each of these three categories as outlined below.

7.2.1. Facility Bias

Validation experiments were conducted at the GSI Land-Based RDTE Facility during facility commissioning in 2008 to determine facility bias relative to zooplankton. These experiments revealed no significant attrition (i.e., decline in live zooplankton densities) associated with either control and treatment track, no significant differences in live organism densities between samples retrieved on intake from matched treatment and control sample ports, and no significant differences in live organism densities between samples retrieved on discharge from matched treatment and control sample ports after either a 5-day or more abbreviated 18 hour holding time. Copies of these experiments and findings are available on request.

7.2.2. Experiment Bias

To minimize experimental bias, the GSI conducts reference toxicant tests on a monthly basis in order to verify the health and sensitivity of the WET test organisms cultured in-house, with the exception of *Selenastrum capricornutum* (green algae). Reference toxicant test data is sent to LSRI by the supplier for test organisms that are obtained commercially, i.e. *Pimephales promelas* (fathead minnow). A species-specific quality control chart is prepared following each reference toxicant test, and the median-lethal concentration (LC_{50}) is compared to the historical mean of previous (maximum n = 20) reference toxicant tests. A median-lethal concentration within two standard deviations of the historical mean indicates that the test organisms are of known and documented quality and may be used for testing. A second measure of experimental bias for WET testing is made through the use of a reference control. The reference control group consists of test organisms in culture water (e.g., dechlorinated laboratory water, hard reconstituted water, etc.), providing optimal conditions for survival. The reference control group is not used for statistical analyses; rather, it provides data regarding the health of the test organisms. The GSI performance measure for the reference control group is average percent survival.

In the case of land-based tests involving chemical analyses, the GSI prepares and analyzes spike and recovery samples to estimate bias resulting from interferences in the matrix and to determine the effectiveness of the analytical method used. In this case, the GSI performance measure for experimental bias is Percent Spike Recovery (SPR) as calculated by the following equation:

$$\text{Percent Spike Recovery (SPR)} =$$
$$\left(\frac{(Measured\ Spiked\ Sample\ Concentration) - \ (Measured\ Unspiked\ Sample\ Concentration)}{Nominal\ Spike\ Concentration}\right) * 100\%$$

Whenever possible, an appropriate sample blank (i.e., medium blank for microbial analysis or matrix blank for chemical analysis), procedural blank, and/or a positive and negative control are run for each set of samples analyzed.

In addition, all equipment and analytical instrumentation used at the land-based facility, is calibrated and/or verified prior to use according to the appropriate SOPs and with the appropriate frequency. Equipment and analytical instrumentation also receive scheduled routine maintenance, which is documented, along with all non-routine maintenance, in the appropriate GSI records. To avoid bias that may result from contamination of samples at the GSI Land-Based RDTE Facility, all sample containers are thoroughly rinsed prior to sample collection and all sample containers are clearly labeled.

7.2.3. Operator Bias

GSI evaluates operator bias for microbial analyses and WET tests by having a second, suitably-qualified operator count at least 10 percent of all experimental units (e.g., IDEXX Quanti-Trays® or test chambers). Analysis occurs immediately following analysis by the first operator and is carried out in a manner such that the second operator does not know the results of the first operator's analysis. The GSI performance measurement for microbial analyses and WET tests is relative percent difference (RPD):

$$\text{RPD} = \left(\frac{(|x_1 - x_2|)}{\frac{x_1 + x_2}{2}}\right) * \ 100\ \%$$

where:

x_1= sample result
x_2 = duplicate sample result

Operator bias relative to zooplankton is evaluated for every treatment discharge sample collected at the GSI Land-Based RDTE Facility. In this situation, one out of every ten slides (i.e., for microzooplankton) or one out of every ten counting wheels (i.e., for macrozooplankton) analyzed by the primary taxonomist is also analyzed by a second, suitably-qualified zooplankton taxonomist. The duplicate analysis is conducted such that the second operator does not know the results of the first operator's analysis. Additionally, one out of every ten control intake or discharge samples is analyzed by a second zooplankton taxonomist. In the event that there are less than ten total control samples collected during a treatment technology performance evaluation, at least one intake or discharge control sample is evaluated, with one slide and one counting wheel analyzed in duplicate.

Operator bias relative to phytoplankton samples collected at the land-based facility is evaluated using at least two treatment discharge samples and at least one control intake/discharge sample per each set of five test trials. In this situation, for every sample analyzed by the primary taxonomist that requires evaluation, a second, suitably qualified taxonomist simultaneously analyzes the same sample using a dual-headed compound microscope. The analysis is conducted such that the second operator does not know the results of the primary operator's analysis, and vice versa.

The GSI performance measurements for operator bias for zooplankton and phytoplankton analysis is the average percent similarity (PSC) of taxonomic identification and average relative percent difference (RPD) of the number of live organisms/entities counted for all second analyses performed. Relative percent difference is calculated using the above formula. The formula for PSC is 1 – ½ *(the sum over all species (*i* = 1 to *n*) of the absolute value of (the proportion of species *i* found by person 1 minus the proportion of species *i* found by person 2). This value is then multiplied by 100 to convert from a proportion to a percent. Percent similarity of taxonomic identification is calculated using the following formula:

$$\boldsymbol{PSC} = \left(\mathbf{1} - \mathbf{0.5}\sum_{\boldsymbol{i}=\mathbf{1}}^{\boldsymbol{K}}|\boldsymbol{a_i} - \boldsymbol{b_i}|\right) \times \mathbf{100}\%$$

where:

where a_i and b_i = the relative proportions of species *i* in the sample found by operator *A* and *B*, respectively

7.3. Accuracy

Accuracy is a measure of the overall agreement of a measurement to a known value. It includes a combination of random error (precision) and systematic error (bias). The GSI measures accuracy with respect to land-based chemical and water quality analyses (including hardness and alkalinity titrations) by using a certified reference standard whenever one is available. This data quality indicator is evaluated by calculating the Percent Difference (%D) between the measured and nominal certified reference standard values using the following equation:

$$\text{Percent Difference (\%D)} =$$

$$\left(\frac{(|x - y|)}{x}\right) * 100\%$$

Where:

x = reference standard nominal concentration
y = reference standard measured concentration

7.4. Representativeness

Representativeness is a qualitative measure of the degree to which data accurately and precisely represents a characteristic of a population parameter at a sampling point or for a process condition or environmental condition. At the GSI Land-Based RDTE Facility, representativeness is achieved through the installation of piping, pumps and sample ports that are similar in characteristics to those installed on a commercial vessel. It is also achieved through the control and treatment tracks being equivalent, from both an engineering standpoint (i.e., in terms of length of piping, number of elbow joins, flow rate, etc.) and a biological standpoint. In addition, the retention tanks located at the facility are sized large enough to allow for the storage of water in physical conditions that mimic those of a ballast tank. Representativeness is also achieved through the collection of sufficient volumes of water that is characteristic of Duluth-Superior Harbor water in terms of species concentration and richness.

7.5. Comparability

Comparability refers to the extent to which findings generated from GSI tests are comparable to findings generated by similar tests (i.e., either conducted at the same location but at different time of the year, or at other institutions) or in the literature. It is a qualitative term that evaluates not only results, but also similarity between sampling and analytical methods.

Results from GSI tests conducted at the land-based facility are comparable because they are conducted following SOPs, which allow for consistency of experimental method regardless of the individuals conducting the study. As such, GSI evaluates comparability by ensuring that all SOPs are correctly implemented. This is achieved through regular technical system audits (see section 15), and the analysis of deviations to SOPs to ensure that they are minor and do not affect data quality.

7.6. Completeness

Completeness is a measure of the percentage of biological/chemical samples measured that are valid out of the total number of collected samples. GSI deems biological and/or chemical samples invalid if they are contaminated, fail to meet the data quality objectives or other QA protocols, are lost through sample destruction, are incorrectly collected or analyzed, and/or if there is insufficient amount of sample for analysis.

For GSI land-based test activities, the performance measure for completeness is Percent Completeness (%C) as calculated by the following equation:

$$\text{Percent Completeness (\%C)} =$$

$$\left(\frac{Number\ of\ Valid\ Measurements}{Total\ Number\ of\ Measurements}\right) * 100\%$$

7.7. Sensitivity

Sensitivity is the capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest. Sensitivity is also indicated by the statistical power associated with the ability of a statistical method to detect significant differences between treatment and control groups, which is increased with increased replication and decreased error/variability. The GSI determines sensitivity of chemical and microbial analysis at the land-based scale of testing. The sensitivity of microbial analyses utilizing an IDEXX® analytical method is reported in the product literature for each type of analysis (i.e., *E. coli*, *Enterococcus spp.*, total heterotrophic bacteria). Determination of the sensitivity of chemical analyses is achieved by calculating the method detection limit (MDL) and limit of quantification (LOQ) of the analytical method used to measure a given parameter of interest by the following equations:

$$\text{Method Detection Limit (MDL)} = SD * t_{(n-1)}$$

Where:
SD = standard deviation of replicates
$t_{(n-1)}$ = Student's t-value for the number of replicates

$$\text{Limit of Quantification (LOQ)} = MDL \times \frac{10}{3}$$

Table 5. GSI Data Quality Objectives for Land-Based Physical/Chemical Analyses.

Data Quality Indicator	Evaluation Process	Performance Measure	GSI Data Quality Objective
Precision	Analyze at least 10 % of samples in duplicate.	Relative Percent Difference (RPD).	< 20 % average RPD.
Bias	*Experiment Bias:* Analysis of spike-recovery samples; ensure proper calibration/verification and maintenance of equipment/analytical instrumentation; ensure proper sample handling to avoid contamination.	Percent Spike Recovery (SPR)	75%-125% average SPR.
Accuracy	Where applicable, use a certified reference standard to determine differences between the measured and nominal reference standard concentrations.	Percent Difference (%D).	< 20 % average %D .
Representativeness	Ensure pre-treatment/control and post-treatment/treatment samples are handled and analyzed in the same manner.	N/A – Qualitative term.	N/A – Qualitative term.
Comparability	Routine procedures are conducted according to appropriate SOPs to ensure consistency between tests. Ensure correct implementation of SOPs.	N/A – Qualitative term.	N/A – Qualitative term.
Completeness	Calculate percentage of valid samples analyzed out of the total number of samples collected.	Percent Completeness (%C)	Greater than 90 %C.
Sensitivity	Determine the method detection limit and limit of quantification for each analyte and analytical method utilized.	Method Detection Limit (MDL) and Limit of Quantification (LOQ)	Dependent upon the analyte and instrumentation.

Table 6. GSI Data Quality Objectives and Criteria for Zooplankton (Organisms >50 μm) Collect at the GSI Land-Based RDTE Facility.

Data Quality Indicator	Evaluation Process	Performance Measure	GSI Data Quality Objective
Precision	Analyze at least two slides or two counting wheels from every sample collected.	Coefficient of variation (%CV).	≤ 20 % CV.
Bias	*Experiment Bias:* Ensure proper calibration/verification and maintenance of equipment/analytical instrumentation; ensure proper sample handling to avoid contamination.	N/A	N/A
	Operator Bias: Ensure a second, suitably-qualified operator analyzes at least 10 % of treatment discharge samples, and 10 % of control intake and discharge samples.	Percent Similarity (PSC) and Relative Percent Difference (RPD)	≥90% average PSC and ≤20% average RPD.
Representativeness	Ensure sample water contains biota representative of harbor water in terms of species composition and richness. Ensure pre-treatment/control and post-treatment/treatment samples are handled and analyzed in the same manner.	N/A – Qualitative term.	N/A – Qualitative term.
Comparability	Routine procedures are conducted according to appropriate SOPs to ensure consistency between tests. Ensure correct implementation of SOPs.	N/A – Qualitative term.	N/A – Qualitative term.
Completeness	Calculate percentage of valid samples analyzed out of the total number of samples collected.	Percent Completeness (%C)	Greater than 90 %C.

Table 7. Data Quality Objectives and Criteria for Phytoplankton (i.e., Entities <50 and >10 μm) Sampled at the GSI Land-Based RDTE Facility.

Data Quality Indicator	Evaluation Process	Performance Measure	GSI Data Quality Objective
Precision	Analyze at least three treatment discharge samples and at least one out of ten control intake/discharge samples (from each set of test trials).	Percent Similarity (PSC)	≥ 60% average PSC between paired replicates.
Bias	*Experiment Bias:* Ensure proper calibration/verification and maintenance of equipment/analytical instrumentation; ensure proper sample handling to avoid contamination.	N/A	N/A
	Operator Bias: Ensure a second, suitably-qualified operator analyzes at least two treatment discharge samples and at least one control intake/discharge sample per each set of five test trials.	Percent Similarity (PSC) and Relative Percent Difference (RPD)	≥60% average PSC and ≤20% average RPD.
Representativeness	Ensure augmented test organisms are representative of those naturally found in Duluth-Superior Harbor. Ensure sample water contains biota representative of harbor water in terms of species composition and richness. Ensure pre-treatment/control and post-treatment/treatment samples are handled and analyzed in the same manner.	N/A – Qualitative term.	N/A – Qualitative term.
Comparability	Routine procedures are conducted according to appropriate SOPs to ensure consistency between tests. Ensure correct implementation of SOPs.	N/A – Qualitative term.	N/A – Qualitative term.
Completeness	Calculate percentage of valid samples analyzed out of the total number of samples collected.	Percent Completeness (%C)	Greater than 90 %C.

Table 8. Data Quality Objectives and Criteria for Microbial Samples.

Data Quality Indicator	Evaluation Process	Performance Measure	GSI Data Quality Objective
Precision	Analyze at least 10 % of samples in duplicate.	Relative Percent Difference (RPD).	< 20 % average RPD.
Bias	*Experiment Bias:* Ensure proper calibration/verification and maintenance of equipment/analytical instrumentation; ensure proper sample handling to avoid contamination.	N/A	N/A
	Operator Bias: Ensure a second, suitably-qualified operator counts at least 10 % of samples.	Relative Percent Difference (RPD).	< 20 % average RPD.
Representativeness	Ensure sample water contains biota representative of harbor water in terms of species composition and richness. Ensure pre-treatment/control and post-treatment/treatment samples are handled and analyzed in the same manner.	N/A – Qualitative term.	N/A – Qualitative term.
Comparability	Routine procedures are conducted according to appropriate SOPs to ensure consistency between tests. Ensure correct implementation of SOPs.	N/A – Qualitative term.	N/A – Qualitative term.
Completeness	Calculate percentage of valid samples analyzed out of the total number of samples collected.	Percent Completeness (%C)	Greater than 90 %C.
Sensitivity	Limit of detection (LOD) is determined for each analysis type, and reported in the product literature.	Limit of Detection (LOD)	Determined by the manufacturer of Colilert™ and Enterolert™, dependant on the sample volume analyzed.

Table 9. Data Quality Objectives and Criteria for GSI Whole Effluent Toxicity (WET) Testing.

Data Quality Indicator	Evaluation Process	Performance Measure	GSI Data Quality Objective
Bias	*Experiment Bias:* Conduct monthly reference toxicity tests on test organisms or obtain reference toxicity test data from the test organism supplier(s);; ensure proper calibration/verification and maintenance of equipment/analytical instrumentation; ensure proper sample handling to avoid contamination.	Determination of the sensitivity of the test organisms relative to historical data using a quality control chart.	LC_{50} value within 2 standard deviations of the historical mean LC_{50}.
	Operator Bias: Ensure a second, suitably-qualified operator analyzes at least 10 % of samples.	Relative Percent Difference (RPD).	< 10 % average RPD.
Representativeness	Ensure test organisms are representative of those naturally found in Duluth-Superior Harbor, and/or recommended by the U.S. EPA. Control groups (reference and dilution control) and treatment groups are handled and analyzed in the same manner.	N/A – Qualitative term.	N/A – Qualitative term.
Comparability	Routine procedures are conducted according to appropriate SOPs to ensure consistency between tests. Ensure correct implementation of SOPs.	N/A – Qualitative term.	N/A – Qualitative term.
Completeness	Calculate percentage of valid samples analyzed out of the total number of samples collected.	Percent Completeness (%C)	Greater than 90 %C.

Table 10. GSI Data Quality Objectives for Water Quality Analyses.

Data Quality Indicator	Evaluation Process	Performance Measure	GSI Data Quality Objective
Precision	Analyze at least 10 % of samples in duplicate.	Relative Percent Difference (RPD).	< 20 % average RPD.
Accuracy	Where applicable, use a certified reference standard to determine differences between the measured and nominal reference standard concentrations.	Percent Difference (%D).	< 20 % average %D.
Representativeness	Ensure pre-treatment/control and post-treatment/treatment samples are handled and analyzed in the same manner.	N/A – Qualitative term.	N/A – Qualitative term.
Comparability	Routine procedures are conducted according to appropriate SOPs to ensure consistency between tests. Ensure correct implementation of SOPs.	N/A – Qualitative term.	N/A – Qualitative term.
Completeness	Calculate percentage of valid samples analyzed out of the total number of samples collected.	Percent Completeness (%C)	Greater than 90 %C.

7.8. GSI Performance Criteria

In order for a test to be valid at the GSI Land-Based RDTE Facility, data quality objectives must be met as well as specific levels of core parameters. These parameters include physical, chemical, biological and operational metrics such as biota abundance, water quality parameters, and system operation. Parameters are checked for validity either prior to initiating a test, or during the test itself. Table 11 details the reference limits (minimum and maximum values) for core parameters that may be applicable to land-based tests. The specific parameters and acceptable ranges will be detailed in the test plan.

Table 11. Reference Limits for Core Parameters: Control/Pre-treatment Intake Samples Collected at the GSI Land-Based RDTE Facility.

Category	Core Parameter	Reporting Units	Acceptable Range for Initiating Testing
Physical/Chemical	Salinity	PSU	0 – 1
	Dissolved Organic Carbon (DOC)	mg/L	> 6
	Particulate Organic Carbon (POC)	mg/L	> 5
	Total Suspended Solids (TSS)	mg/L	> 24 mg/L; can be artificially augmented to 50
	Dissolved Oxygen	mg/L	5 - 15
	pH	--	7 - 9
	Temperature	°C	5 - 25
	Water Flow Rate	m^3/hr	200 - 400
Biological	Zooplankton	Live Organisms/m^3	Live organisms ≥50 μm in minimum dimension should be present in a total density of 100,000 to 1,000,000 live individuals per m^3, and should consist of at least 5 species from at least 3 different phyla/divisions.
	Chlorophyll *a*	μm/L	3 - 15
	Phytoplankton	Live Individuals/mL	Entities ≥10 μm and less than 50 μm in minimum visible dimension should be present in a total density of not less than 500 cells per mL (can be spiked into intake to achieve 1,000-1,800 cells/ per mL), and should consist of at least 5 species from at least 3 different phyla.
	Heterotrophic Bacteria Density	Viable bacteria/mL	Heterotrophic bacteria should be present in a density of at least 1,000 MPN per mL.

8. SPECIAL TRAINING REQUIREMENTS/CERTIFICATION

8.1. Project-Specific QAQC Training for Research Personnel

Project-specific QAQC training is provided at least every two years to all relevant GSI personnel. Generally this training is conducted prior to the start of research activities. Training may consist of seminars or classes, or on-the-job training. For example, those GSI personnel involved in land-based research activities at the GSI facility in Superior, Wisconsin receive training on the GSI land-based QAPP prior to the start of testing in May/June. Training generally involves (1) an overview of GSI's Quality System; (2) specifics on GSI project-specific QAPPs; and (3) Data verification and validation; and (4) technical assessments and auditing.

8.2. Project-Specific Training for Research Personnel

Training is provided to those personnel involved with specific activities that require specialized occupational health and safety training. For example, all GSI personnel that enter retention tanks at the GSI Land-Based RDTE Facility are required to be "Confined Space" Certified. All personnel involved with active substances at the bench-scale and/or at the GSI Land-Based RDTE Facility receive "Material Safety Data Sheet (MSDS)" training. Those involved with the discharge of treated water at the GSI Land-Based RDTE Facility also receive training on the GSI's Emergency Discharge Response Plan, and use of the safety shower and eye washes. Similar emergency training is also provided to those handling chemicals in the laboratory.

Training is also provided to those individuals that are required to operate specialized equipment associated with the GSI Land-Based RDTE Facility, or for sample collection and/or analysis purposes. GSI Senior Scientists are responsible for ensuring that technicians under their supervision possess and maintain adequate proficiency, expertise, and knowledge in their respective work disciplines. It is also their responsibility to ensure that these personnel are adequately trained in applicable policies, procedures, requirements, and their scope of application.

8.3. Contracting-Entity Training

Where GSI activities are undertaken at facilities operated by other entities (i.e. UW-S or UM-D), the GSI adheres to the training requirements of those facilities and makes sure that all relevant training is carried out. For example, specific training is provided by LSRI on occupational health and safety issues concerning chemical spills, eye care and safety, fire safety, first aid, ergonomics, and laboratory safety. LSRI personnel involved in GSI testing activities at the GSI Land-Based RDTE facility also receive "Quality Systems and Good Laboratory Practices (GLP)" training.

9. DOCUMENTS AND RECORDS

9.1. Document and Records Management

9.1.1. Delegation of Authority

The GSI PI is responsible for delegating authority for the development of GSI documents and records, as well as providing a timeframe in which to start and complete the document. In general, it is this person—the "Document Manager"—who is also responsible for the document's management. The Document Manager works in conjunction with the GSI PI to determine document format, scope, audience, length, etc. The Document Manager also works with GSI quality management officers to coordinate assignment of a specific and unique GSI document code.

Once complete, the Document Manager is responsible for distributing the document to the GSI PI, and other GSI senior research personnel (if required) for review. She/he is also responsible for maintaining a master version of the document on file, and also on GSI SharePoint. Once complete, the final version of the document is also saved in the appropriate subfolder on GSI SharePoint.

9.1.2. Format

At a minimum, all GSI documents and records must include the following specifications. The unique document code must be placed in the top right hand corner of the document header as well as the date and number of pages. Codes are provided by the GSI Senior Quality Systems Officer. The document cover page must include the GSI logo as well as the title and authors.

9.1.3. Revision

Changes to documents must be recorded on a record of amendments sheet that is attached to the original document. The record must describe the revision as well as the date. GSI quality management personnel are responsible for updating the record of amendments for all quality documents (i.e., QMP, QAPPs, SOPs, etc).

9.1.4. Maintenance

GSI quality management personnel are responsible for maintaining on file and on GSI SharePoint a matrix of all GSI documents and records. The matrix includes the following headings: document type (i.e., SOP, QAQC, findings report, form, etc), document code, title, manager, status and date.

GSI quality management personnel are also responsible for maintaining all documents and records for a period of five years. Electronic versions of GSI documents and records are saved to the GSI SharePoint website (www.greatshipsinitiative.info). Hard copies of GSI documents and records, including raw data, are scanned and also saved to the GSI SharePoint website. Due care and diligence is taken to properly dispose of documents and records that are no longer required after the five year period has lapsed. Disposal procedures involve electronic deletion of documents and records from the GSI SharePoint website and the personal computers of GSI personnel, as well as manual shredding of hard copies.

9.2. Specific Documents and Records

9.2.1. Quality Management Plan (QMP)

This document details the structure of the GSI's quality system from an organizational perspective. It covers all aspects of GSI's commitment to quality including policies and procedures; criteria for and areas of application; roles, responsibilities, and authorities; and assessment and response. It is the framework for planning, implementing, documenting, and assessing the GSI's quality assurance and quality control (QAQC) activities.

The GSI Senior Quality Systems Officer is responsible for preparing the QMP, with the document based on the U.S. EPA's "*EPA Requirements for Quality Management Plans*" to the greatest extent possible. The QMP is distributed to the GSI PI for review in draft form. Once a draft is finalized, the document is approved and forwarded to GSI senior research personnel and QAQC officers. Draft and final copies of the document are posted to the GSI SharePoint intranet website; the final version may also be posted to the GSI public website. The GSI's QMP is valid for a maximum period of five years, with an annual review and revision (as needed) occurring at the end of each calendar year.

9.2.2. Quality System Annual Report

The GSI Quality System Annual Report documents the GSI's quality system activities over the previous calendar year, including a summary of the year's projects and activities; a summary of the year's project-specific audits, assessments and responses; a list of quality system documentation and SOPs developed during the year; a list of quality management training GSI personnel received during the year; a discussion on the status of the GSI quality system including strengths, weaknesses, successes and problems, and recommendations for improvements; and an assessment of the adequacy of the GSI QMP and recommended changes. The GSI Senior Quality Systems Officer is responsible for preparing the report in conjunction with the GSI Senior QAQC Officer. Once a draft is finalized, the document is then passed on to the GSI PI for approval. The final report is distributed to relevant GSI research team personnel. Final copies are also posted to the GSI SharePoint intranet website.

9.2.3. Quality Assurance Project Plans (QAPPs)

GSI's Quality Assurance Project Plans (QAPP) describes the activities undertaken by GSI to assure the quality and credibility of its project-specific research findings, i.e., at the land-based facility or bench-scale of testing. Each QAPP covers all aspects of quality assurance/quality control (QAQC) relative to the specific project area, including data quality indicators, evaluation processes, performance measures and acceptance criteria; instrument certification and calibration; personnel training requirements; documents and records; data management; and QAQC assessments and response actions.

The GSI Senior Quality Systems Officer, in conjunction with the GSI Senior QAQC Officer, is responsible for developing the QAPPs. The plans follow the format of the U.S. Environmental Protection Agency's (EPA's) "*EPA Guidance for Quality Assurance Plans*" to the greatest extent possible. Draft QAPPs are distributed to relevant GSI senior research personnel for review and comment. Once a draft is finalized, the documents are then passed on to the GSI PI for review and approval. Draft and final copies of QAPPs are posted to the GSI SharePoint intranet website; the final versions may also be posted to the GSI public website. All QAPPs, once approved, are valid for a period of five years, though they are reviewed annually and revised as needed.

9.2.4. Standard Operating Procedures (SOPs)

SOPs are used to implement all GSI test activities. This facilitates consistent conformance to technical and quality system requirements and increases data quality. The SOPs include both programmatic and technical processes and procedures such as organism culturing; operation of the GSI Land-Based RDTE facility; sample collection, labeling, analysis and custody; and safety. Appendix 1 provides a list of GSI SOPs relevant to land-based test activities.

GSI SOPs are developed by the relevant GSI senior research personnel in conjunction with the GSI Senior Quality Systems Officer and GSI Senior QAQC Officer. The GSI Senior Quality Systems Officer is responsible for distributing finalized SOPs to the GSI PI for approval. Draft and final copies of all SOPs are posted to the GSI SharePoint website; the final versions are also posted to the GSI public website. All GSI SOPs are updated on an as-needed basis.

To date approximately 50 SOPs have been finalized, with many more in draft form or planned. The SOPs follow a common format and include specific QAQC procedures and metrics. GSI SOPs are grounded in published standard methods. They are also consistent with international and domestic guidelines where they exist. All GSI SOPs are subject to periodic review and revision to assure that the most up to date approaches are employed.

9.2.5. Field and Laboratory Notebooks

Bound field and laboratory notebooks, each having a unique identification code, are used to record observations, sampling details, and laboratory and field measurements. Notebooks are also used to record instrument and equipment calibration and maintenance information. GSI personnel are responsible for maintaining the notebooks on site, creating electronic copies, and posting to the GSI SharePoint website for storage and archiving.

9.2.6. Forms and Records

Specific forms are used to record sample collection and analysis data. All relevant GSI senior research personnel are responsible for ensuring that the forms are correctly filled out. They are also responsible for maintaining the forms on file, creating electronic copies, and posting to the GSI SharePoint website for storage and archiving. In general, hard copies of all forms are stored in three-ring binders, each with a unique identification code.

Specific forms are also used to record sample custody, handling and storage information. Chain of custody forms are employed only when an outside laboratory is contracted to conduct sample analyses. All relevant GSI senior research personnel are responsible for ensuring that the forms are correctly filled out at the time of changes to sample custody, and sample handling and storage. They are also responsible for maintaining the forms on file, creating electronic copies, and posting to the GSI SharePoint website for storage.

In addition, specific forms are used to record operation, maintenance and safety information. The GSI Land-Based RDTE Facility Operations Manager is responsible for ensuring that all forms associated with safety (i.e., confined space entry permit forms, daily safety checklist) and operation and maintenance of the land-based test facility are correctly filled out. It is the responsibility of the GSI Land-Based RDTE Facility Operations Manager to ensure that equipment maintenance and instrument calibration is properly documented, and that forms are maintained on file, and also posted to the GSI SharePoint website for storage.

9.2.7. Personnel Records

GSI quality management personnel are responsible for maintaining on the GSI SharePoint site copies of all GSI personnel resumes, and training and certification documents. The documents are updated on an as-needed basis by the relevant personnel.

9.2.8. Test Findings and Other GSI Products

NEMWI personnel are responsible for maintaining on file and posting to the GSI SharePoint website all test findings and other GSI products. These include applicant and public reports of test findings, public summaries of test findings, peer-reviewed scientific papers and reports, outreach documents, and conference presentations. NEMWI personnel are also responsible for distributing copies of these documents to relevant parties, and posting to the GSI public website, if required.

9.2.9. Quality Assurance/Quality Control Records

GSI assesses its quality system on a project by project (i.e., test by test) basis using a variety of tools. In this situation, one project/test is defined as a series of trials of a specific ballast treatment system. For example, one test may constitute a set of five trials of a ballast treatment system at the GSI land-based facility. The purpose, procedural details, and implementation frequency of each of these assessment tools are outlined below.

GSI QAQC Officers assess the implementation of project-specific QAPPs and SOPs during each test of a ballast treatment system. At the end of the test duration, the officers provide reports to the GSI Senior Quality Systems Officer and GSI PI. The reports include a table listing deviations to the specific QAPP associated with the testing and a table listing deviations to the specific SOPs that were used during the testing. GSI QAQC Officers also verify data recording and archiving procedures by randomly evaluating data recording forms and field notebooks for completion, compliance and correct storage procedures.

Following completion and verification of a data set associated with a specific ballast treatment test, GSI QAQC Officers determine if the data quality objectives outlined in the relevant GSI QAPP have been successfully met. GSI QAQC Officers also determine if the performance criteria outlined in the relevant GSI QAPP have been successfully met. Results are provided in reports submitted to the GSI Senior Quality Systems Officer and GSI PI; final copies are stored on GSI SharePoint.

10. DATA GENERATION AND ACQUISITION

10.1. Data Generation

As detailed in Section 5, GSI land-based biological research activities take place at the GSI's Land-Based RDTE Facility located in Superior, WI. At the facility, ambient conditions are employed as the physical/chemical challenge conditions, except that certain parameters may be augmented to meet IMO or ETV requirements. These will be detailed in the test plan. Biological challenge conditions are also ambient except that organism densities in the smaller of the two plankton size classes (i.e., 10 - 50 μm) can be enhanced to assure consistency with IMO G8 required thresholds.

Flow control valves and system logic assure that sample flow rates are equivalent and proportional to intake and discharge flow rates throughout each operation. Flow rates are recorded every 5 seconds during the test trials from three locations at automated valves on the control track, treatment track, and on the discharge line. Pressure readings are also recorded every 5 seconds throughout the facility.

Samples for water chemistry and water quality analysis can be collected during intake, tank retention and discharge and will be specified in the test plan. The water chemistry and water quality parameters that are measured are also specific to the treatment technology being evaluated, and will be detailed in each test plan.

In addition, temperature, dissolved oxygen, turbidity and pH are measured regularly throughout the retention period by two identical multi-parameter probes (calibrated according to manufactures specifications) placed, one each, into the central midwater of the control and test tanks. A calibrated, hand-held instrument is also used to measure temperature, salinity, chlorophyll fluorescence, and dissolved oxygen from one of the control sample collection tubs, one the pre-treatment sample collection tubs, and one of the post-treatment sample collection tubs during intake. These parameters are also measured during discharge from one control sample collection tub and two or three treatment sample collection tubs. The specifics of these measurements will be detailed in the test plan.

Sample water for analysis of viable organisms is simultaneously collected from the replicate sample ports identified in figure 5 into identical 3.8 m^3 collection tubs during each intake or discharge operation. Volumes retained vary with the operation (intake versus discharge) and treatment (control versus treatment). The water in each collection tub constitutes an independent time integrated replicate sample of the experimental water mass.

For live analysis of organisms greater than 50 μm in minimum dimension, during the intake operation, i.e. the filling of the treatment and control 200 m^3 retention tanks, the following time-integrated sample volumes are generally collected by continuous flow from the intake lines simultaneously, though the specific sample location and volume will be detailed in the test plan:

- 2 – 3.8 m^3 from the pre-treatment intake line,
- 2 – 3.8 m^3 from the control intake line, and
- 2 – 3.8 m^3 from the immediate post-treatment intake line.

During discharge:

- One 2 – 3.8 m^3 sample of control discharge, and
- Three samples of up to 3.8 m^3 each (total volume 11.4 m^3) of treated discharge.

Immediately after filling (and collection of phytoplankton, microbial, and chemistry samples), the entire sample volumes are drained from the sample collection tubs and concentrated through 35 μm (50 μm diagonal dimension) plankton nets into 1 L cod-ends and are immediately transported in an insulated cooler to the on-site mobile laboratory for microscopic examination. Analysis occurs within two hours of sample collection, with samples stored in coolers during the interim. See *GSI/SOP/LB/RA/SC/6 - Procedure for Zooplankton Sample Collection*.

For live analysis of organisms 10 – 50 μm in minimum dimension, one sample of 1 L is generally collected immediately after filling from the pre-treatment sample collection tub and one sample of 1 L is collected from the immediate post-treatment sample collection. During discharge, one sample of 1 L is collected from the control tank via sample collection tub, and three samples of 1 L each are collected from the replicate treatment sample collection tubs. Again, the specific sample location and volume will be detailed in the test plan. Analysis occurs on-site within 1.5 hours of sample collection, with samples stored in coolers during the interim. Prior to analysis, samples are concentrated through a 10 μm plankton net and stored in a 25 mL sample container. See *GSI/SOP/LB/RA/SC/3 - Procedure for Algae/Small Protozoa Sample*

Collection.

For bacteria analysis, control and treatment samples are collected and analyzed for heterotrophic bacteria, two specific indicator pathogens: *E. coli* and enterococci, and viable toxigenic *Vibrio cholerae*. Samples are generally collected as one liter whole water samples as follows:

- On intake, three are collected immediately after filling from the pre-treatment sample collection tubs, and three are collected from the post-treatment sample collection tubs.
- On discharge, three are collected from a control sample collection tub, and three are collected from three treatment sample collection tubs.

All samples are collected according to *GSI/SOP/LB/RA/SC/4 – Procedure for Microbial Sample Collection*, and are immediately transported in an insulated cooler to the LSRI and analyzed as individual replicates.

For Whole Effluent Toxicity (WET) analysis, GSI conducts Standard WET tests to determine the potential for residual toxicity of treated discharge water. Three freshwater species are used as test organisms—the cladoceran *Ceriodaphnia dubia*, fathead minnows (*Pimephales promeas*) and the green alga *Selanastrum capriconutum*. See *GSI/SOP/BS/RA/WET/1 - Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to Ceriodaphia dubia*, *GSI/SOP/BS/RA/WET/2 - Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to the Fathead Minnow* (*Pimephales promelas*), and *GSI/SOP/BS/RA/WET/3 - Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to the Green Alga* (*Selenastrum capricornutum*). Again, the specific sample location and volumes will be specified in the test plan.

10.2. Data Acquisition

Live/dead status of organisms > 50 μm is determined within two hours of concentration. Samples are split and simultaneously analyzed for smaller species (rotifers, copepod nauplii, veligers, etc.) in a Sedgewick Rafter counting chamber at a magnification of 40X to 100X, and larger species (e.g., crustanceans) in a Ward's Counting Wheel at a magnification of 20 to 30X,. Live/dead status is determined based on active/reactive movement. Where live densities are high, dead organisms are counted first, and then all organisms are counted following a lethal treatment and live densities deduced. Where live densities are low, the sample is only examined for live organisms. Complete protocols are provided in *GSI/SOP/LB/RA/SA/2 - Procedure for Zooplankton Sample Analysis*.

Live analysis of 10-50 μm organisms (algae and protists) occurs within 1.5 hours of sample collection. Samples are concentrated through a 10 μm net and stored in a 25 mL container. A 1.5 mL subsample of the concentrated sample is transferred to a 2 mL container and 4 μL of Fluorescein Diacetate (FDA) stock solution is added. The subsample incubates in the dark for 5 minutes. The sample is then mixed and 1.1 mL immediately transferred to a Sedgwick-Rafter cell, covered and placed on the stage of a microscope that is set for simultaneous observation using brightfield and epifluorescence. At least two horizontal transects are counted (an area representing > 1 mL of original water). Entities and cells are characterized as alive if cell contents have obvious green fluorescence. Counting and measurement follow standard procedures for individuals (length and width), colonies (number of cells, cell length and width) and filaments (e.g., number of cells, cell length and width or total filament length if cells could not be discerned). Total counted volume is calculated later based on records of transect length and width. Complete protocols are provided in *GSI/SOP/LB/RA/SA/1 - Procedure for Algae/Small Protozoan Sample Analysis*.

Microbial analysis of each of the sample replicates commences at LSRI typically within one hour of sample collection. Analysis methods include the SimPlate® for HPC Method for enumeration of viable heterotrophic bacteria (see *GSI/SOP/BS/RA/MA/1 - Procedure For Quantifying Heterotrophic Plate Counts (HPCs) Using IDEXX's SimPlate® for HPC Method*); and the utilization of the Colilert® (see *GSI/SOP/BS/RA/MA/4 - Procedure for the Detection and Enumeration of Total Coliforms and E. coli Using IDEXX's Colilert®*) and Enterolert™ (see *GSI/SOP/BS/RA/MA/3 - Procedure for the Detection and Enumeration of Enterococcus using Enterolert*™) (IDEXX Laboratories, Inc.; Westbrook, Maine), respectively, for E. coli and enterococci enumeration. RNA and DNA colony blots are prepared (see *GSI/SOP/BS/RA/MA/6 - Procedure For Colony Blot Preparation for the Enumeration of Culturable Vibrio cholerae and Presence of ctxA Gene*) and filters which exhibit colony growth are shipped to the Maryland Pathogen Research Institute at the University of Maryland (College Park, MD) for analysis of potential viable toxigenic V. cholerae with a commercial DFA kit specific for serogroup O1 (New Horizons Diagnostics).

Samples collected for analysis of selected water quality parameters are immediately placed into a cooler containing ice to cool the samples. Within several hours of collection the samples are transported to LSRI for analysis or further preservation. The samples collected for analysis of total organic carbon (TOC) are preserved by acidifying to 0.2% with hydrochloric acid. Dissolved organic carbon (DOC) samples are filtered through an appropriately-sized filter and acidified. The samples for analysis of total or dissolved organic carbon are then refrigerated at 4 ˚C until they are analyzed. Total suspended solids (TSS) samples are either processed immediately or refrigerated until analyzed.

Analysis of samples is conducted following the appropriate SOPs, i.e., *GSI/SOP/BS/RA/C/3 – Procedures for Measuring Organic Carbon in Aqueous Samples, GSI/SOP/BS/RA/C/8 - Procedure for Analyzing Total Suspended Solids (TSS)*. The TSS samples are filtered through a washed and pre-weighed filter. After the filtering process is completed, the filters are oven dried at 103-105 ˚C to constant weight. The TOC and DOC samples are analyzed using the combustion-infrared method (Shimadzu Total Organic Carbon Analyzer). Particulate organic carbon (POC) values are determined as the difference between the TOC and DOC concentrations. All analyses are completed within the U.S. EPA/ETV specified hold times for the particular analyses.

If a treatment system is utilizing an active substance, samples are collected at various locations during the fill and discharge of the holding tanks to monitor concentrations of the active substance. The specific test methods used for monitoring active substance concentrations and concentrations of disinfection by-products (DBP) are specific to the particular active substance(s) used by the ballast water treatment system and are provided in the test plan. Concentrations of active substance and DBP found in the discharge from the treatment tank are used to determine proper disposal of the treated water. Concentrations of the active substance present in exposure solutions used in WET testing are also determined.

In addition, GSI measures facility operational and maintenance parameters during all operational cycles. A Human Machine Interface (HMI) is installed at the facility to automate this process. The HMI has a 15” color touch display and is capable of detailing valve positions, pressure from the pressure meters, fill level of the ballast retention tanks, and flow rates in the control and treatment lines, etc. The HMI reads and records data from all the position meters, pressure meters, flow meters and level indicators every 5 seconds for the entire duration of the operational cycle. The HMI console collects and records the data and saves the information to a specific file following completion of each operational cycle. An external data computer, attached to the HMI, is then used to store the data files. The files can be opened in Microsoft Excel or any other spreadsheet program for viewing and/or analysis. Influent water quality is also monitored and recorded in the same manner using pH, DO, turbidity and temperature sensors just prior to the treatment system.

GSI also monitors chemical usage for systems that involve chemicals. The specific monitoring processes however, depend on the actual treatment system itself and are therefore outlined in the Test Plan.

11. SAMPLE LABELING, HANDLING AND CUSTODY

All GSI land-based samples are labeled in a clear and precise manner following *GSI/SOP/G/RA/SC/3 - Procedure for Labeling Samples Collected at the GSI Land-Based RDTE Facility*. This ensures proper identification in the field and/or tracking in the laboratory. Unique sample codes are assigned to each type of sample and these codes are used for the sample containers, field and laboratory data sheets, log books, chain of custody forms, and database entries. Sample labels are prepared and placed on sample collection containers prior to sample preparation/collection.

The individual collecting the sample is personally responsible for the handling and custody of the sample until it is transferred to the individual responsible for analyzing the sample. The GSI QAQC Officer present at the GSI Land-Based RDTE Facility determines whether proper custody procedures are followed during the field work and decides if additional samples are required due to improper sample handling.

Chain-of-custody procedures are strictly followed for all samples that are shipped to a non-GSI laboratory (i.e., to a contracted analytical laboratory) so that the possession of a sample from the time of its collection until the time of its analysis is traceable and documentable. These procedures not only guarantee the integrity of a sample (i.e., that it was properly prepared, preserved and/or handled leading up to analysis), but also alleviates the possibility of sample mix-ups and/or extraneous contamination.

For samples under Chain-of-Custody (i.e., those shipped to a non-GSI laboratory), a Chain-of-Custody form must accompany each shipment (i.e., one form can accommodate multiple samples). The original record shall accompany the shipment, and a copy shall be retained by the individual relinquishing the sample. The method of shipment, i.e., couriers' name, and other pertinent information, should be entered in the "Remarks" box.

All relevant GSI senior personnel are responsible for ensuring that the Chain-of-Custody forms are correctly filled out at the time of changes to sample custody, and sample handling and storage. They are also responsible for maintaining the forms on file, creating electronic copies, and posting to the GSI SharePoint website for storage.

12. QUALITY CONTROL REQUIREMENTS

The GSI's quality control requirements relative to its land-based activities are summarized in table 12, though more detailed information will be provided in the test plan. All of these requirements and associated acceptance criteria and corrective actions ensure that data generated is acceptable and credible.

Table 12. Quality Control Requirements at the GSI Land-Based RDTE Facility.

Applicability	Quality Control Requirement	Frequency	Acceptance Criteria	Corrective Action
Operational	Proper documentation and archiving of all operational data	Following each set of tests of a ballast treatment system.	Qualitative spot-checks of documents and data storage/archiving procedures.	Problems identified by the spot-checks will be documented and included in a corrective action report
Health and Safety	Adequately trained personnel.	As required.	Qualitative spot-checks of documents and data storage/archiving procedures.	Problems identified by the spot-checks will be documented and included in a corrective action report
	Completion of the *GSI Land-Based Facility Daily Safety Check List.*	Daily		
	Completion of the *GSI Confined Space Entry Permit Form.*	As required.		
Chemical/Physical Water Parameters	Dependent on test plan.	Dependent on test plan.	Dependent on test plan.	Dependent on test plan.
Biological Water Parameters	Dependent on test plan.	Dependent on test plan.	Dependent on test plan.	Dependent on test plan.
Sample Collection	Ensure correct implementation of SOPs.	Periodically	N/A - qualitative	Problems identified by the spot-checks will be documented and included in a corrective action report
Sample Analysis	Ensure correct implementation of SOPs.	Periodically	N/A - qualitative	Problems identified by the spot-checks will be documented and included in a corrective action report
	Validation of data quality indicators.	Dependent on test plan.	Dependent on test plan	Dependent on test plan
Data Analysis	Dependent on test plan.	Dependent on test plan.	Dependent on test plan.	Dependent on test plan.
Documents and Records	Proper recording, storage and archiving of all documents and records.	Regularly (i.e., monthly).	Qualitative spot-checks of documents and records recording, storage and archiving procedures.	Problems identified by the spot-checks will be documented and included in a corrective action report
Sample Labeling, Handling and Custody	Checking of sample labels by a second individual to ensure that the same codes are not used for more than one individual sample.	At the time of sample labeling.	Qualitative spot-checks of sample labeling, handling and custody procedures.	Problems identified by the spot-checks will be documented and included in a corrective action report
	Determination as to whether proper custody procedures were followed during the field work and also if additional samples are required.	Following completion of a sampling trial.	Qualitative spot-checks of sample labeling, handling and custody procedures.	Problems identified by the spot-checks will be documented and included in a corrective action report
	Proper recording, storage and archiving of all Chain-of-Custody forms.	Regularly (i.e., monthly).	Qualitative spot-checks of Chain-of-Custody form recording, storage and archiving procedures.	Problems identified by the spot-checks will be documented and included in a corrective action report
Equipment and Instruments	Calibration or verification of analytical equipment/instrumentation. Maintenance checks of equipment, and proper documentation and archiving of maintenance data.	Dependent on the type of equipment; in some cases, daily.	Qualitative spot-checks of documents and data storage/archiving procedures.	Problems identified by the spot-checks will be documented and included in a corrective action report

13. INSTRUMENT/EQUIPMENT TESTING, INSPECTION AND MAINTENANCE

The GSI Land-Based RDTE Facility Operations Manager (Mr. Tyler Schwerdt) is responsible for ensuring that all instruments and equipment, with the exception of meters and analytical equipment, located at the GSI Land-Based RDTE Facility are inspected and maintained according to the manufacturer's manual. He is also responsible for ensuring that all personnel undertaking maintenance of specific instruments and pieces of equipment are suitably qualified and that they have read and understood the manual for each device prior to undertaking any inspection and/or maintenance procedures. Inspection and maintenance procedures for specific pieces of equipment, i.e., the bay pump and injection pumps, are detailed in *GSI/SOP/LB/G/O/1 - Procedure for Operating the GSI Land-Based RDTE Facility*.

In addition, Mr. Schwerdt is responsible for ensuring that all activities related to testing, inspection and maintenance of instruments and equipment at the GSI land-based facility are correctly documented. He is also responsible for maintaining the documents on file, creating electronic copies, and posting to the GSI SharePoint website for storage. QAQC spot-checks of these forms and the processes used to complete and maintain them will be undertaken periodically by GSI QAQC Officers. Problems identified by the spot-checks will be documented and included in a corrective action report.

Laboratory instrument/equipment verification/calibration, maintenance, and documentation are the responsibility of the GSI senior staff members from each analytical area. That is, GSI senior staff members are responsible for only the equipment in their respective laboratories that will be used for the specific treatment technology being tested.

14. DATA ANALYSIS AND MANAGEMENT

14.1. Data Processing, Review and Verification, and Storage

Biological and chemical data is recorded by hand (using indelible ink) on pre-printed data collection forms and/or in bound laboratory notebooks that are uniquely-identified and are specific to the treatment technology being tested. The types of biological and chemical data collected include: sample collection data (e.g., date, time, and location of collected samples), water quality and chemistry analysis data (e.g., TSS, TOC, and active substance concentration), microbial analysis data (e.g., sample preparation, incubation, and direct counts), phytoplankton analysis data (e.g., number of live and number of dead entities), zooplankton analysis data (e.g., sample concentration; number of dead, total, and live organisms), and whole effluent toxicity test data (e.g., test set up, direct counts, and test take down).

The data that are recorded on pre-printed data collection forms are secured in uniquely-identified three ring binders, specific to the type of data and to the treatment technology. Biological and chemical data that are recorded by hand are entered into either a MS Access Database that was designed, developed, and is maintained by the GSI Database Manager, or the data are entered into a MS Excel Spreadsheet. The electronic data files are stored on the LSRI's secured Local Area Network (LAN) that can be accessed only by relevant GSI personnel. The GSI Database Manager is the single point of control for access to the LSRI LAN. The LSRI LAN is automatically backed up every 24 hours. The electronic data files are also stored on the GSI's internal SharePoint website, which acts as a secondary data backup/storage mechanism. All original raw data from verification testing of each treatment technology are stored in a climate-controlled, secure archive room at the LSRI for five years after the final report is finalized.

In-tank water quality data (e.g., temperature, pH, dissolved oxygen, salinity, turbidity, and chlorophyll-a) is measured every fifteen minutes during each retention period and automatically recorded in a Microsoft (MS) Excel spreadsheet. Facility data (e.g., flow rates and pressure measurements) are electronically recorded every five seconds during intake and discharge. This data is exported to MS Excel for subsequent analysis, and stored by AMI Engineers on a secure network, as well as on GSI SharePoint for addition storage and archiving.

A percentage of data that is recorded by hand and entered into MS Access or Excel is verified against the original raw data, this also includes verification of formulas/calculations (i.e., hand-calculation of data) done using MS Access or Excel. The percentage of verified raw data depends on the amount of raw data that was generated, and ranges from 10 % to 100 % of the original raw data. Data validation is detailed in Section 7 of this QAPP. This section also details the acceptable values, where appropriate, for the following quality objectives: accuracy, precision, completeness, comparability, representativeness, and sensitivity.

14.2. Data Analysis

The statistical method used to analyze data is dependent on the type of data (i.e., zooplankton, phytoplankton, etc), and the relationships being analyzed (i.e., control vs. treatment, intake vs. discharge, treatment discharge vs. regulatory standard) and will be specified in the test plan. In all cases, appropriate and widely-used statistical software packages are used to generate and report mean values (± standard deviation or standard error) across groups. In addition, Analysis of Variance (ANOVA) is used to compare means across control and treatment, intake and discharge groups, etc. A difference between means/groups is significant at $p<0.05$.

15. QUALITY ASSURANCE ASSESSMENT AND OVERSIGHT

GSI quality management personnel utilize various tools to assess the GSI quality system. Based on these activities, GSI quality personnel produce several types of reports including project-specific QAQC reports and an annual GSI quality system report.

15.1. Assessment

GSI assesses its quality system on a project by project (or test by test) basis using a variety of tools. In this situation, one project/test is defined as a series of trials of a specific ballast treatment system, i.e., one test may constitute a set of five trials of a ballast treatment system at the GSI land-based facility. The purpose, procedural details, and implementation frequency of each of these assessment tools are outlined below.

15.1.1. Project-Specific QAPP Audits

GSI QAQC Officers assess the implementation of project-specific QAPPs during each test of a ballast treatment system. At the end of the test duration, the officers provide a report to the GSI Senior Quality Systems Officer and GSI PI. The report includes a table listing deviations to the specific QAPP associated with the testing. The following table headings are to be used:

- QAPP Section
- QAPP Page No.
- Description
- Deviation/Inconsistency
- Date
- GSI Personnel
- Reconciliation/Corrective Act

The report also includes an assessment of personnel training requirements and certification, as well as procedures for storing and archiving documents and records; sample labeling, handling and custody requirements; and instrument and equipment maintenance. GSI QAQC Officers post final copies of the QAPP audit reports to the GSI SharePoint website for archiving and storage.

15.1.2. Project-Specific SOP Audits

GSI QAQC Officers assess the implementation of project-specific SOPs during each test of a ballast treatment system. At the end of the test duration, the officers provide a report to the GSI Senior Quality Systems Officer and GSI PI. The report includes a table listing deviations to the specific SOPs that were used during the testing. The following table headings are to be used:

- SOP Code
- SOP Title
- Description
- Deviation/Inconsistency
- Date
- GSI Personnel
- Reconciliation/Corrective Act

GSI QAQC Officers post final copies of the SOP audit reports to the GSI SharePoint website for archiving and storage.

15.1.3. Project-Specific Data Recording and Archiving Audits

Following completion of test activities associated with a specific ballast treatment test, GSI QAQC Officers verify data recording and archiving procedures by randomly evaluating data recording forms and field notebooks for completion, compliance and correct storage procedures. This includes the GSI Land-Based RDTE Facility Daily Safety Check List, zooplankton enumeration datasheets, phytoplankton enumeration datasheets, sampling station logs, chain of custody forms, etc. GSI QAQC Officers also undertake regular random data verification checks by comparing electronic records (i.e., in database or Excel format) with raw datasheets (i.e., paper forms). This is a manual inspection process and though rather time consuming, is an essential procedure for discovering errors. Findings are summarized in a report provided to the GSI Senior Quality Systems Officer and GSI PI. Final reports are saved to GSI SharePoint for storage and archiving.

15.1.4. Project-Specific Data Quality Assessments

Following completion and verification of a data set associated with a specific ballast treatment test, GSI QAQC Officers determine if the data quality objectives outlined in the relevant GSI QAPP have been successfully met. Findings are summarized in a series of tables detailing the data quality indicators by type of analysis, e.g., zooplankton, phytoplankton, microbes, etc. Reports are provided to the GSI Senior Quality Systems Officer and GSI PI; final copies are stored on GSI SharePoint.

15.1.5. Project-Specific Performance Criteria Assessments

Following completion and verification of a data set associated with a specific ballast treatment test, GSI QAQC Officers also determine if the performance criteria outlined in the relevant GSI QAPP have been successfully met. Findings are summarized in a table detailing the performance criteria and test results. The table is provided in a report to the GSI Senior Quality Systems Officer and GSI PI. Final copies of the report are saved to GSI SharePoint for storage and archiving.

15.2. Response

15.2.1. Corrective Action Reports

GSI quality management personnel convene to discuss quality system audits and assessment outcomes following completion of a specific ballast treatment test. Personnel use the results of audits and assessments to develop recommendations and directives for actions to correct work or data that do not conform to GSI quality standards. They then compile a report listing the recommendations and directives. This report is provided to the GSI PI, relevant GSI senior research team personnel and to those individuals involved in the follow-up to ensure visibility and timeliness. Reports are also posted to the GSI SharePoint website for storage and archiving.

15.2.2. Quality System Annual Report

The GSI Senior Quality Systems Officer is responsible for writing an annual report of GSI quality system activities. The report is to be completed in the first quarter of each year for the previous calendar year's activities. The report includes:

- A summary of the year's projects and activities;
- A summary of the year's project-specific audits, assessments and responses;
- A list of quality system documentation and SOPs developed during the last year;
- A list of quality management training GSI personnel received during the last year;
- A discussion on the status of the GSI quality system including strengths, weaknesses, successes and problems, and recommendations for improvements; and
- An assessment of the adequacy of the GSI QMP and recommended changes.

Once drafted, the GSI Senior Quality Systems Officer sends the report to the GSI Senior QAQC Officer for review and comment. A finalized version is then sent to the GSI PI. Finalized reports are also posted to the GSI SharePoint website for storage and archiving, and distributed to relevant GSI research team members.

APPENDIX 1.

Matrix of Relevant GSI Standard Operating Procedures (SOPs).
Note: SOPs available from http://www.nemw.org/GSI/protocols.htm

Document Type	Document Code	Title	Scale	Category	Subcategory
SOP	GSI/SOP/G/A/RK/1	Procedure for Record Keeping	General	Administration	Record Keeping
SOP	GSI/SOP/G/RA/DM/1	Procedure for Data Entry, Data Quality Control and Database Management	General	Research Activities	Data Management
SOP	GSI/SOP/G/RA/SC/2	Procedure for Custody of GSI Land-Based RDTE Facility Samples	General	Research Activities	Sample Custody
SOP	GSI/SOP/G/RA/SC/3	Procedure for Labeling Samples Collected at the GSI Land-Based RDTE Facility	General	Research Activities	Sample Custody
SOP	GSI/SOP/BS/RA/WET/1	Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to *Ceriodaphia dubia*	Bench-Scale and Land-Based	Research Activities	Chronic Residual and Whole Effluent Toxicity
SOP	GSI/SOP/BS/RA/WET/2	Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to the Fathead Minnow (*Pimephales promelas*)	Bench-Scale and Land-Based	Research Activities	Chronic Residual and Whole Effluent Toxicity
SOP	GSI/SOP/BS/RA/WET/3	Procedure for Assessing Chronic Residual Toxicity of a Ballast Treatment System to the Green Alga (*Selenastrum capricornutum*)	Bench-Scale and Land-Based	Research Activities	Chronic Residual and Whole Effluent Toxicity
SOP	GSI/SOP/BS/RA/MA/1	Procedure For Quantifying Heterotrophic Plate Counts (HPCs) Using IDEXX's SimPlate® for HPC Method	Bench-Scale and Land-Based	Research Activities	Microbial Analysis
SOP	GSI/SOP/BS/RA/MA/3	Procedure for the Detection and Enumeration of Enterococcus using Enterolert™	Bench-Scale and Land-Based	Research Activities	Microbial Analysis
SOP	GSI/SOP/BS/RA/MA/4	Procedure for the Detection and Enumeration of Total Coliforms and E. coli Using IDEXX's Colilert®	Bench-Scale and Land-Based	Research Activities	Microbial Analysis
SOP	GSI/SOP/BS/RA/MA/5	Procedure for the Detection and Enumeration of Male-Specific (F+) Coliphage Using Double Agar Layer Technique (DAL)	Bench-Scale and Land-Based	Research Activities	Microbial Analysis
SOP	GSI/SOP/BS/RA/MA/6	Procedure For Colony Blot Preparation for the Enumeration of Culturable Vibrio cholerae and Presence of ctxA Gene	Bench-Scale and Land-Based	Research Activities	Microbial Analysis
SOP	GSI/SOP/BS/RA/MP/1	General Microbiology Preparation Procedures	Bench-Scale and Land-Based	Research Activities	Microbial Analysis

SOP	GSI/SOP/BS/RA/C/1	Procedure for Analyzing the Concentration of Ozone in Water	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/BS/RA/C/2	Procedure for Determining Total Residual Oxidants (TRO) in Water	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/BS/RA/C/3	Procedures for Measuring Organic Carbon in Aqueous Samples	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/BS/RA/C/4	Procedure for Determining Percent Transmittance (%T) of Light in Water at 254 nm	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/BS/RA/C/5	Procedure for Measuring Organic Compounds using High Performance Liquid Chromatography (HPLC)	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/BS/RA/C/6	Procedure for Analyzing Total Residual Chlorine Concentrations in Water	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/BS/RA/C/7	Procedure for Analyzing Hydrogen Peroxide Concentrations in Water	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/BS/RA/C/8	Procedure for Analyzing Total Suspended Solids (TSS)	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/BS/RA/C/9	Procedure for pH Meter Calibration and pH Measurement for Ballast Treatment Systems Utilizing Basic pH as the Active Substance	Bench-Scale and Land-Based	Research Activities	Chemistry
SOP	GSI/SOP/LB/G/O/1	Procedure for Operating the GSI Land-Based RDTE Facility	Land-Based	General	Operation
SOP	GSI/SOP/LB/G/O/2	Procedure for Sampling and Testing Water Prior to Waste Water Treatment Facility Reception	Land-Based	General	Operation
SOP	GSI/SOP/LB/G/O/3	Procedure for Cleaning the Retention Tanks and Other Equipment at the GSI Land-Based RDTE Facility	Land-Based	General	Operation
SOP	GSI/SOP/LB/G/O/4	Procedure for Transferring Treated Water to the City of Superior Waste Water Treatment Facility	Land-Based	General	Operation
SOP	GSI/SOP/LB/G/O/5	Procedure for Injecting Organisms and Solids into the GSI Land-Based RDTE Facility	Land-Based	General	Operation
SOP	GSI/SOP/LB/G/O/7	Procedure for Solids Resuspension After Retention at the GSI Land-Based RDTE Facility	Land-Based	General	Operation
SOP	GSI/SOP/LB/G/S/1	Procedure for Ensuring Worker Health and Safety at the GSI Land-Based RDTE Facility	Land-Based	General	Safety

SOP	GSI/SOP/LB/RA/SC/1	Procedure for Collecting Biological Sample Water Via In-Line Sample Ports	Land-Based	Research Activities	Sample Collection
SOP	GSI/SOP/LB/RA/SC/2	Procedure for Collecting Biological Samples From Within The Retention Tanks Using A Submersible Pump	Land-Based	Research Activities	Sample Collection
SOP	GSI/SOP/LB/RA/SC/3	Procedure for Algae/Small Protozoa Sample Collection	Land-Based	Research Activities	Sample Collection
SOP	GSI/SOP/LB/RA/SC/4	Procedure for Microbial Sample Collection	Land-Based	Research Activities	Sample Collection
SOP	GSI/SOP/LB/RA/SC/5	Procedure for MS-2 Bacteriophage Sample Collection	Land-Based	Research Activities	Sample Collection
SOP	GSI/SOP/LB/RA/SC/6	Procedure for Zooplankton Sample Collection	Land-Based	Research Activities	Sample Collection
SOP	GSI/SOP/LB/RA/SC/8	Procedure for Collecting Physical/Chemical Data and Samples at the GSI Land-Based RDTE Facility	Land-Based	Research Activities	Sample Collection
SOP	GSI/SOP/LB/RA/SA/1	Procedure for Algae/Small Protozoan Sample Analysis	Land-Based	Research Activities	Sample Analysis
SOP	GSI/SOP/LB/RA/SA/2	Procedure for Zooplankton Sample Analysis	Land-Based	Research Activities	Sample Analysis